



SMC advice issued in March 2014:

- Afatinib (Giotrif®)
- Aflibercept (Zaltrap®)
- Alogliptin (Vipidia®)
- Dapagliflozin (Forxiga®)
- Darunavir (Prezista®)
- Insulin degludec (Tresiba®)
- Lenalidomide (Revlimid®)
- Saxagliptin (Onglyza®)
- Solifenacin and tamsulosin (Vesomni®)
- Teriflunomide (Aubagio®)
- Ustekinumab (Stelara®)
- Zonisamide (Zonegran®)

SMC advice issued in April 2014:

- Fluticasone/vilanterol 92/22mcg inhalation powder (Relvar®)



Prescribing Changes

Fluticasone /vilanterol 92/22 mcg* inhalation powder (Relvar®)

The SMC has recently approved the use of Relvar® Ellipta® in patients with severe COPD. NHS Tayside has placed the drug as a 3rd line option in COPD. Its once daily administration may be beneficial in patients with poor compliance with currently available twice daily preparations e.g. Seretide® 500 Accuhaler® & Symbicort® 200/6 or 400/12 Turbohaler®. There are safety concerns with this new product. [CLICK HERE](#) for the UKMi product safety assessment report for Relvar®.

The main concerns are that it is unclear that the inhaler is a preventer rather than a reliever, mainly due to its name and the fact that the inhaler and packaging are blue for the lower strength & the higher strength has a blue lid.

Once the foil pack is opened and the desiccant removed, the product has a relatively short in-use shelf life of 6 weeks. Many patients with asthma or COPD keep more than one opened device in different locations so they don't forget to use it. This could increase the chances of patients using out of date products. A warning should be added to the dispensing label to inform patients of the short expiry date once opened.

Patients should be counselled on the following issues:

1. Relvar® is a preventative inhaler NOT a reliever inhaler
2. Relvar® has a short in-use shelf life of 6 weeks
3. Relvar® is the brand name of the drug. Ellipta® is the device name

*Higher strength—184/22mcg—licensed for asthma only. SMC advice for asthma due June 2014.

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Ensure® Plus Commence Oral nutritional supplement

Ensure® Plus Commence is a starter pack containing various flavours of Ensure® Plus Milkshake Style that is intended to allow patients to try a selection of flavours before deciding preferences for their Oral nutritional supplement (ONS) prescription. Unlike the rest of the Abbott adult nutrition product range available on the NHS Tayside Area Formulary (several Ensure® Plus products, Ensure® Twocal and Enshake®), Ensure® Plus Commence does not attract a rebate and therefore costs NHS Tayside in the region of £115K alone to prescribe.

Ensure® Plus Commence has therefore been removed from the NHS Tayside Area Formulary. On initial prescription of ONS, prescribe one of the recommended standard 1.5kcal/mL products from the [Abbott adult nutritional supplement range](#) in a range of flavours to establish patient preferences. This can be done by adding 'mixed flavours' to the prescription.



Drug Safety Updates

Please follow link - [Volume 7, Issue 9, April 2014](#)

MHRA Press Release - [New advice for domperidone](#)

Medicine	Indication	Local recommendation category	Comments and useful links
Afatinib 20mg, 30mg, 40mg, 50mg film-coated tablets (Giotrif®) (920/13) - Full submission	As monotherapy, for the treatment of epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor-naïve adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating EGFR mutations).	Hospital Only - Oncology Supplied via a Patient Access Scheme	SMC advice SPC link (20mg) SPC link (30mg) SPC link (40mg) SPC link (50mg)
Aflibercept 25mg/mL concentrate for solution for infusion (Zaltrap®) (878/13) - Resubmission	In combination with irinotecan/5-fluorouracil/folinic acid (FOLFIRI) chemotherapy, aflibercept is indicated in adults with metastatic colorectal cancer (mCRC) that is resistant to or has progressed after an oxaliplatin-containing regimen.	Hospital Only - Oncology Supplied via a Patient Access Scheme	SMC advice SPC link
Alogliptin, 25mg, 12.5mg, 6.25mg, film-coated tablets (Vipidia®) (937/14) - Full submission	For adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control in combination with other glucose lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control.	Not recommended	SMC advice
Dapagliflozin 5mg and 10mg film-coated tablets (Forxiga®) (799/12) - Resubmission	For use in adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control in combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control. SMC restriction: In combination with insulin, when insulin with diet and exercise, does not provide adequate glycaemic control.	GP under the direction of Diabetes team Endocrinology Specialist List (Formulary - restricted use in combination with metformin)	SMC advice SPC link Avoid if eGFR < 60mL/min or with loop diuretic or ≥ 75 yrs
Darunavir 400mg, 800mg film-coated tablets and oral suspension 100mg/mL (Prezista®) (948/14) - Abbreviated submission	Darunavir co-administered with low dose ritonavir in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in paediatric patients 12 to 17 years of age and at least 40kg body weight who are: antiretroviral therapy (ART) naïve; or, ART-experienced with no darunavir resistance associated mutations and who have plasma HIV-1 RNA <100,000 copies/mL and CD4+ cell count ≥100 cells/mm ³ . SMC restriction: in patients <18 years, to be prescribed under the supervision of specialists in paediatric HIV.	Hospital Only - Paediatrics Under direction of paediatric HIV specialist in Lothian or Glasgow	SMC advice SPC link
Insulin degludec (Tresiba®) 100units/mL solution for injection in pre-filled pen or cartridge and 200units/mL solution for injection in pre-filled pen (856/13) - Resubmission	Treatment of diabetes mellitus in adults.	Not recommended	SMC advice
Lenalidomide 2.5mg, 5mg, and , 10mg, hard capsules (Revlimid®) (942/14) - Full submission	For the treatment of patients with transfusion-dependent anaemia due to low- or intermediate-1-risk myelodysplastic syndromes associated with an isolated deletion 5q cytogenetic abnormality when other therapeutic options are insufficient or inadequate.	Hospital Only - Haematology Restricted to when blood transfusion insufficient or inadequate	SMC advice SPC link
Saxagliptin (Onglyza®) 2.5mg & 5mg film-coated tablets (958/14) - Non-submission	Monotherapy in adult patients aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance.	Not recommended	SMC advice

Medicine	Indication	Local recommendation category	Comments and useful links
Solifenacin succinate plus tamsulosin hydrochloride 6mg / 0.4mg modified release tablet (Vesomni®) (945/14) - Abbreviated submission	For the treatment of moderate to severe storage symptoms (urgency, increased micturition frequency) and voiding symptoms associated with benign prostatic hyperplasia in men who are not adequately responding to treatment with monotherapy.	Non Formulary - Absence of clinician demand	SMC advice SPC link
Teriflunomide, 14mg, film-coated tablets (Aubagio®) (940/14) - Full submission	Treatment of adults with relapsing remitting multiple sclerosis (MS). SMC restriction: as an alternative to treatment with interferon beta or glatiramer acetate. Teriflunomide is not expected to be used for the treatment of patients with highly active disease.	Hospital Only - Neurology Supplied via a Patient Access Scheme	SMC advice SPC link Protocol in development
Ustekinumab 45mg solution for injection in pre-filled syringe (Stelara®) (944/14) - Full submission	Alone or in combination with methotrexate, for the treatment of active psoriatic arthritis in adult patients when the response to previous non-biological disease-modifying anti-rheumatic drug therapy has been inadequate. SMC restriction: for use in patients with active psoriatic arthritis who have failed on, or are unsuitable for, treatment with an anti-TNF drug.	Hospital Only Rheumatology Specialist List	SMC advice SPC link 2nd line Biologic
Zonisamide 25mg, 50mg and 100mg capsules (Zonegran®) (949/14) - Abbreviated submission	As adjunctive therapy in the treatment of partial seizures, with or without secondary generalisation, in adolescents, and children aged 6 years and above. SMC restriction: on advice from specialists (paediatric neurologists or paediatricians with an expertise in epilepsy).	GP under the direction of Paediatric Neurology Clinic	SMC advice SPC link

SMC Advice issued in April 2014 (publication date 7 April 2014) - further SMC advice issued in April to be included in Tayside DTC supplement No 137 (April/May 2014)

SMC website: www.scottishmedicines.org.uk

Medicine	Indication	Local recommendation category	Comments and useful links
Fluticasone furoate/vilanterol 92/22 micrograms inhalation powder (Relvar®) (953/14) - Full submission	Symptomatic treatment of adults with chronic obstructive pulmonary disease (COPD) with a forced expiratory volume in 1 second (FEV ₁) <70% predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy. SMC restriction: in patients with severe COPD (FEV ₁ <50% predicted normal).	Formulary 3rd line choice 1st choice - Seretide® 500 Accuhaler® 2nd choice - Symbicort® 200/6 or 400/12 Turbohaler®	SMC advice SPC link NB: This is not a reliever medicine & has a 6 week expiry

'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 \(including Individual Patient Treatment Requests\)](#)'

Tayside Area Formulary (TAF) Updates - Mar/Apr 2014

TAF Section	Drug(s)/topic	Changes
Specialist formulary lists and formulary development	Respiratory	Tiotropium (Spiriva Respimat®) removed from Respiratory specialist formulary list. Tiotropium (Spiriva Respimat®) may be prescribed when appropriate for patients who cannot use other formulary devices.
3.1 & netFormulary*	Bronchodilators - long acting beta2 agonists	Formoterol fumarate added back in to formulary as 3rd choice long-acting beta2 agonist in COPD.
3.2 & netFormulary*	Inhaled corticosteroids - compound preparation	In last months DTC supplement 135 it stated that Seretide 100 Accuhaler® and Seretide 250 Accuhaler® were removed from the formulary. This was an error as they remain in the formulary for the treatment of asthma (only Seretide 500 Accuhaler® licensed for use in COPD). See Adult Asthma - Inhaled Medicine Chart . Fluticasone furoate/vilanterol (Relvar Ellipta® ▼ 92/22micrograms) added to formulary as 3rd choice ICS/LABA for COPD. See SMC advice on page 3.
6.1 & netFormulary* Endocrinology Specialist List	Other antidiabetic drugs	Dapagliflozin▼ indication in combination with insulin, when insulin with diet and exercise, does not provide adequate glycaemic control added to formulary and Endocrinology specialist formulary list (GPs may prescribe under direction of the Diabetes Clinic). See SMC advice on page 2.
9.4	Oral nutrition	Ensure® Plus Commence removed from Abbott adult nutritional supplement range included within the formulary. Link added to updated Abbott adult nutritional supplement range . On initial prescription of ONS, prescribe one of the recommended standard 1.5kcal/mL products as 'mixed flavours' on the prescription.
10.1.3 Rheumatology Specialist List	Cytokine modulators	Ustekinumab indication for active psoriatic arthritis alone or in combination with methotrexate in patients who have responded inadequately to, or are unsuitable for, treatment with an anti-TNF added to formulary and Rheumatology specialist formulary list (Hospital-Only). See SMC advice on page 3.
Wound Management Formulary		Section 6 - Pressure Ulcers and Section 10 - Wound complications: Fungating wounds have been updated.

* Tayside netFormulary currently under development and not available for open access.

SMC Briefing Note:
[Click here](#) for March 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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