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ADTC Newsletter New Drugs and Therapeutic Advances



Outlined in this newsletter are the recommendations for new drugs which have been through the locally agreed process (see appendix 1).

Please remember that the ADTC advises prescribers **not** to prescribe any drug that has not been recommended by Scottish Medicines Consortium (SMC) or has not yet been considered by SMC.

Where a medicine is not recommended for use by the Scottish Medicines Consortium (SMC) for use in NHS Scotland, including those medicines not recommended due to non-submission, this will be noted by the Area Drug and Therapeutics Committee New Drugs & Formulary Sub Group and the medicine will not be added to the NHS Forth Valley Formulary.

Where a medicine that has not been accepted by the SMC or NHS Health Improvement Scotland (HIS) following their appraisal on clinical and costeffectiveness, there are Individual Patient Treatment Request (IPTR) and Peer Approved Clinical System (PACS) processes which provides an opportunity for clinicians i.e. hospital Consultants or General Practitioners to pursue approval for prescribing, on a "case by case" basis for individual patients

A copy of these policies can be found at the Pharmacy page on the Quality Improvement Website on the following link:

https://guidelines.staffnet.fv.scot.nhs.uk/pharmacyand-precribing/

GUIDELINES AND POLICIES

All guidelines and policies approved by the Area Drug and Therapeutics Committee can be found on the Quality Improvement Website on the link below.

http://guidelines.staffnet.fv.scot.nhs.uk/

Drugs Not Approved By the Scottish Medicines Consortium

Prescribing of SMC non-recommended drugs is monitored nationally by the Information Services Directorate (ISD) of the NHS National Services Scotland and reported to the Forth Valley Primary Care Pharmacy Services. As part of our locally agreed process, practices will be routinely notified on a quarterly basis of any items which are not recommended for use, and advised to review therapy.

The Acute Services will similarly be monitoring the use of SMC non-recommended drugs and will feedback usage to their Executives via the Finance Report.

All information provided by this newsletter constitutes the most current advice of the Forth Valley Area Drug and Therapeutic Committee. All SMC information and decisions are correct at time of issue, but may be liable to change in the future. For full SMC advice on specific drugs please refer to the SMC website www.scottishmedicines.org

Category Classification

Drugs Approved / Not Recommended By SMC

Category 1	Available in line with national guidance (link to SMC Detailed Advice Document (DAD) included)
Category 2	Available in line with local guidance for prescribing
Category 3	Available from a specialist centre in another NHS Board
Category 4	Not available as not recommended for use in NHS Scotland (link to SMC Detailed Advice Document (DAD) included)
Category 5	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines (link to local guidance if appropriate)
Category 6	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts

Drug (approved by SMC)	SMC Advice	New Drugs Sub-group Outcome	Area of Prescribing
Relugolix 40mg, estradiol 1mg, norethisterone acetate 0.5mg film- coated tablets (Ryeqo®) SMC Number 2442	Accepted for restricted use within NHSScotland. Indication under review: treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. SMC restriction: for use in patients who have failed or are unsuitable for conventional therapies (first line treatments), such as tranexamic acid, hormonal contraceptives and intrauterine delivery systems.	Category 1 — available in line with national guidance	By specialist services and continuation in primary care

SMC NOT RECOMMENDED - The following drugs for the indication stated are all classified as Category 4 i.e. Not available as not recommended for use in NHS Scotland (link to SMC Detailed Advice Document (DAD) included) Defatted powder of Arachis hypogaea L., **Indication under review:** treatment of patients aged 4 to 17 years with a confirmed diagnosis of peanut allergy. Palforzia® may semen (peanuts) 0.5mg, 1mg, 10mg, 20mg, 100mg oral powder in capsules for opening be continued in patients 18 years of age and older. Palforzia® and 300mg oral powder in sachet should be used in conjunction with a peanut-avoidant diet. (Palforzia®) SMC Number 2487 Zanubrutinib 80mg hard capsules **Indication under review:** as monotherapy for the treatment of (Brukinsa®) SMC Number 2452 adult patients with Waldenström's macroglobulinaemia (WM) who have received at least one prior therapy, or in first line treatment for patients unsuitable for chemo-immunotherapy.

ADTC DECISIONS <u>PENDING/CHANGES</u> FOR SMC APPROVED DRUGS									
Drug (approved by SMC)	SMC Advice	Previous decision	Updated FV Formulary position	Area of Prescribing					
Risankizumab 150mg solution for injection in a pre-filled syringe or pen (Skyrizi®) SMC Number 2459 risankizumab-skyrizi- abbreviated-final-march- 2022-for-website.pdf (scottishmedicines.org.uk)	Accepted for use restricted use with NHSScotland Indication under review: Alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adults who have had inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs) SMC restriction: (i) patients whose disease has not responded adequately or who have been intolerant to two previous conventional disease-modifying antirheumatic drugs (DMARDs) therapies but have not received biologic DMARD therapy (biologic-naïve population); (ii) patients whose disease has not responded adequately to conventional DMARDs and one or more tumour necrosis factor (TNF) inhibitors (biologic-experienced population); and (iii)	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Category 5 — not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines	N/A					

	ADTC DECISIONS PENDING/CHANGE	S FOR SMC APPROV	ED DRUGS				
Drug (approved by SMC)	SMC Advice	Previous decision Updated FV Formulary Proposition					
	patients in whom TNF inhibitors are contraindicated or not tolerated						
Beclometasone dipropionate / formoterol fumarate dihydrate / glycopyrronium 172mcg / 5mcg / 9mcg (Trimbow®) SMC Number 2334 https://www.scottishmedici nes.org.uk/media/7044/be clomestasone-trimbow-hd- abbreviated-final-feb-2021- amended-30622-for- website.pdf	Accepted for use within NHSScotland. Indication under review: maintenance treatment of asthma, in adults not adequately controlled with a maintenance combination of a longacting beta2-agonist and high dose of inhaled corticosteroid, and who experienced one or more asthma exacerbations in the previous year	Category 6 — Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Category 2 – available in line with local guidance	Acute and Primary Care			
Delta-9- tetrahydrocannabi nol 2.7mg and cannabidiol 2.5mg per 100 microlitre spray (Sativex® Oromucosal Spray) SMC Number 2473 https://www.scottishmedici nes.org.uk/media/7097/del ta-9- tetrahydrocannabinod- sativex-final-aug-2022-for- website.pdf	Accepted for use within NHSScotland. Indication under review: As treatment for symptom improvement in adult patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Decision Pending				
Estradiol 1mg / micronised progesterone 100mg capsules (Bijuve®) SMC Number 2502 https://www.scottishmedici nes.org.uk/media/7098/est radiol-micronised- progesterone-bijuve-abb- final-aug-2022-for- website.pdf	Accepted for use within NHSScotland. Indication under review: continuous combined hormone replacement therapy (HRT) for estrogen deficiency symptoms in postmenopausal women with intact uterus and with at least 12 months since last menses. The experience in treating women older than 65 years is limited.	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Decision Pending				
Tofacitinib 5mg film-coated tablets (Xeljanz®) SMC Number 2463 https://www.scottishmedici nes.org.uk/media/7092/tof acitinib-xeljanz-final-aug- 2022-amended-070922- for-website.pdf	Accepted for use within NHSScotland. Indication under review: for the treatment of adult patients with active ankylosing spondylitis (AS) who have responded inadequately to conventional therapy.	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Decision Pending				
Trifarotene 50 microgram/g cream (Aklief®)	Accepted for use within NHSScotland.	Category 6 — Not routinely available as local	Decision Pending				

	ADTC DECISIONS PENDING/CHANGES	S FOR SMC APPROV	ED DRUGS	
Drug (approved by SMC)	SMC Advice	Previous decision	Updated FV Formulary position	Area of Prescribing
smc Number 2441 https://www.scottishmedici nes.org.uk/media/7093/trif arotene-aklief-abbreviated- final-jan-2022-amended- 130722-for-website.pdf Brolucizumab 120mg/mL solution for injection and solution for injection in pre- filled syringe (Beovu®) SMC Number 2508 brolucizumab-beovu-abb- final-sept-2022-for- website.pdf (scottishmedicines.org.uk)	Indication under review: for the cutaneous treatment of acne vulgaris of the face and/or the trunk in patients from 12 years of age and older, when many comedones, papules and pustules are present. Accepted for restricted use within NHSScotland. Indication under review: in adults for the treatment of visual impairment due to diabetic macular oedema. SMC restriction: treatment of visual impairment due to diabetic macular oedema in adults with best corrected visual acuity 75 Early Treatment Diabetic Retinopathy Study letters or less at baseline.	implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts Category 6 — Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Decision Pending	
Filgotinib 100mg and 200mg film- coated tablets (Jyseleca®) SMC Number 2475 filgotinib-jyseleca-resub- final-sept-2022-for- website.pdf (scottishmedicines.org.uk)	Accepted for restricted use within NHSScotland. Indication under review: for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). Filgotinib may be used as monotherapy or in combination with methotrexate. SMC restriction: in adults with moderate disease (a disease activity score [DAS28] of 3.2 to 5.1) when intensive therapy with 2 or more conventional DMARDs has not controlled the disease well enough, in combination with methotrexate or as monotherapy when methotrexate is contraindicated.	Category 6 — Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Category 5 — not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines	N/A
Imlifidase 11mg powder for concentrate for solution for infusion (Idefirix®) SMC Number 2445 https://www.scottishmedici nes.org.uk/media/7099/iml ifidase-idefirix-final-july- 2022-for-website.pdf	Accepted for use within NHSScotland. Indication under review: for desensitisation treatment of highly sensitised adult kidney transplant patients with positive crossmatch against an available deceased donor. The use of imlifidase should be reserved for patients unlikely to be transplanted under the available kidney allocation system including prioritisation programmes for highly sensitised patients.	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Category 3 — available from specialist centre in another NHS board	N/A
Ozanimod 0.23mg, 0.46mg and 0.92mg hard	Accepted for use within NHSScotland. Indication under review: for the treatment of adult patients with	Category 6 — Not routinely available as local implementation	Decision Pending	

	ADTC DECISIONS PENDING/CHANGE	S FOR SMC APPROV	ED DRUGS	
Drug (approved by SMC)	SMC Advice	Previous decision	Updated FV Formulary position	Area of Prescribing
capsules (Zeposia®) SMC Number 2478 ozanimod-zeposia-final- sept-2022-for-website.pdf (scottishmedicines.org.uk)	moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent.	plans are being developed or the ADTC is waiting for further advice from local clinical experts		
Upadacitinib 15mg, 30mg, and 45mg prolonged- release tablets (Rinvoq®) SMC Number 2510 upadacitinib-rinvoq-uc- abb-final-sept-2022-for- website.pdf (scottishmedicines.org.uk)	Accepted for use within NHSScotland. Indication under review: for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent.	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Decision Pending	
Belimumab 120mg and 400mg powder for concentrate for solution for infusion (Benlysta®) SMC Number 2477	Accepted for restricted use within NHSScotland. Indication under review: Add-on therapy in patients aged 5 years and older with active, autoantibodypositive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g., positive anti-dsDNA and low complement) despite standard therapy. SMC restriction: in adults with evidence for at least one marker of serological disease activity (low complement, positive anti-dsDNA) and a Safety of Estrogens in Lupus Erythematosus National Assessment-Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score ≥10.	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Decision Pending	
Belimumab 200mg solution for injection in pre- filled pen or pre- filled syringe (Benlysta®) SMC Number 2530	Accepted for restricted use within NHSScotland. Indication under review: add-on therapy in adult patients with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g. positive anti-dsDNA and low complement) despite standard therapy. SMC restriction: in adults with evidence for at least one marker of serological disease activity (low complement, positive anti-dsDNA) and a Safety of Estrogens in Lupus Erythematosus National Assessment-Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score ≥10.	Category 6 — Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Decision Pending	
Buprenorphine/nal oxone 1.4mg/0.36mg,	Accepted for restricted use within NHSScotland.	Category 6 – Not routinely available as local	Decision Pending	

	ADTC DECISIONS PENDING/CHANGES	S FOR SMC APPROV	ED DRUGS	
Drug (approved by SMC)	SMC Advice	Previous decision	Updated FV Formulary position	Area of Prescribing
2.9mg/0.71mg, 5.7mg/1.4mg, 8.6mg/2.1mg, 11.4mg/2.9mg sublingual tablets (Zubsolv®) SMC Number 2123	Indication under review: substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. The intention of the naloxone component is to deter intravenous misuse. Treatment is intended for use in adults and adolescents over 15 years of age who have agreed to be treated for addiction. SMC restriction: for use in patients for whom methadone is not suitable.	implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts		
Faricimab 120mg/mL solution for injection (Vabysmo®) SMC Number 2499	Accepted for restricted use within NHSScotland. Indication under review: For the treatment of adult patients with visual impairment due to diabetic macular oedema (DMO) SMC restriction: treatment of visual impairment due to DMO in adults with best corrected visual acuity (BCVA) of 75 Early Treatment Diabetic Retinopathy Study (ETDRS) letters or less at baseline.	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Decision Pending	
Finerenone 10mg and 20mg film- coated tablets (Kerendia®) SMC Number 2486	Accepted for use within NHSScotland. Indication under review: for the treatment of chronic kidney disease (stage 3 and 4 with albuminuria) associated with type 2 diabetes in adults.	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Decision Pending	
Levofloxacin 5mg/mL plus dexamethasone 1mg/mL eye drops solution (Ducressa®) SMC Number 2511	Accepted for use within NHSScotland. Indication under review: for prevention and treatment of inflammation, and prevention of infection associated with cataract surgery in adults. Consideration should be given to official guidance on the appropriate use of antibacterial agents.	Category 6 — Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Decision Pending	
Sodium zirconium cyclosilicate 10g powder for oral suspension (Lokelma®) SMC Number 2515	Accepted for restricted use within NHSScotland. Indication under review: for the treatment of hyperkalaemia in adult patients SMC restriction: in the emergency care setting for the treatment of acute, life-threatening hyperkalaemia alongside standard care.	Category 6 – Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts	Decision Pending	
Upadacitinib 15mg prolonged-release tablet (Rinvoq®) SMC Number 2480	Accepted for use within NHSScotland. Indication under review: for the treatment of active ankylosing	Category 6 — Not routinely available as local implementation	Decision Pending	

ADTC DECISIONS <u>PENDING/CHANGES</u> FOR SMC APPROVED DRUGS									
Drug (approved by SMC)	SMC Advice	Previous decision	Updated FV Formulary position	Area of Prescribing					
	spondylitis (AS) in adult patients who have responded inadequately to conventional therapy.	plans are being developed or the ADTC is waiting for further advice from local clinical experts							
Velmanase alfa 10mg powder for solution for infusion (Lamzede®) SMC Number 2466	The Scottish Medicines Consortium (SMC) has completed its initial assessment of the evidence for the above product using the ultra-orphan framework: Indication under review: enzyme replacement therapy for the treatment of non-neurological manifestations in patients with mild to moderate alphamannosidosis.	•	Category 3 - available from a specialist centre in another NHS Board	N/A					

Formulary Changes/Additions/Amendments

The following key changes to the Forth Valley Formulary have been agreed by the New Drugs & Formulary Group following recent formulary section reviews. Relevant *ScriptSwitch*® messages to support prescribers in primary care have been added to the clinical system and relevant changes will be reflected in the EMIS FV e-Formulary when it is next updated.

The Forth Valley Formulary can be accessed from the staff net homepage under quick links - click on clinical resources then FV formulary or access via the intranet link Forth Valley Formulary or via the Forth Valley Formulary internet site https://pharmacies.nhsforthvalley.com/local-quidance/forth-valley-formulary/

Formulary Review

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Chapter 3 - Respiratory								
	he local and national guidance	!						
Products with low carbon/n	eutral footprint annotated with	n a green leaf						
In newly prescribed patient	s, preference is to use Dry Po	wder Inhaler devices (DPIs) ra	ther than Metered Dose					
Inhalers (MDIs) where clinic	cally appropriate							
Preferred inhalers have bee	en annotated as 1 st or 2 nd line o	choices in the Formulary						
Key changes are summarise	ed below							
Drug	Addition	Deletion	Comments					
	Antimus	carinics						
Bevespi Aerosphere® as	✓							
MDI choice for LAMA +								
LABA								
	LAB							
• •	removed – not commonly pre	escribed as monotherapy. Sho	uld be used in					
combination with ICS for as								
	SAB							
Drug	Addition	Deletion	Comments					
Salbutamol Easyhaler®	√		DPI choice					
Terbutaline	Terbutaline √							
	brand prescribing of salbutam		Ventolin Evohaler® has a					
high carbon footprint. In newly prescribed patients prescribe as the brand Salamol®.								

SABAs								
Drug	Addition	Deletion	Comments					
Easyhaler	√							
Beclomethasone®								
Easyhaler Budesonide®	√							
Soprobec®	√		Replaces Clenil® as preferred MDI brand – more cost-effective					

Link to information on steroid emergency card added

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Drug	Addition	Deletion	Comments
Fobumix Easyhaler®	✓		
Luforbec®	√		Replaces Fostair as preferred MDI brand – more cost-effective

High carbon footprint for Flutiform® noted

Triple combination therapy

Drug	Addition	Deletion	Comments
Trimbow [®]	√		MDI as choice for
			asthma
Trixeo Aerosphere MDI®	√		Alternative MDI choice
·			to Trimbow® for
			patients with COPD

Peak Flow meters / spacer devices

Preferred brands changed to more cost effective choices – Easy peak flow meter and Easychamber spacer device

Antihistamines

Drug	Addition	Deletion	Comments
Fexofenadine	√		
Alimemazine		✓	

The following changes were also agreed but these products will not be added to the formulary. To be used in preference in newly prescribed patients

- Kelhale® MDI to be used instead of QVAR® MDI
- Fixkoh Airmaster® to be used instead of Seretide Accuhaler®
- Avenor[®] MDI to be used instead of Seretide[®] MDI
- Tiogiva® to be used instead of Spiriva®/Braltus®
- The use of Flixotide Accuhaler® 125mcg and 250mcg rather than Flixotide Evohaler® 125mcg and 250mcg when clinically appropriate

Other Formulary Changes

- YES VM® vaginal moisturiser added to the Formulary for use in post-menopausal women with symptoms of vaginal dryness when HRT has not been effective or considered inappropriate. Can be prescribed in Primary Care.
- Descovy® as a 2nd line alternative to emtricitabine/tenofovir disoproxil for PrEP. Specialist hospital use only.
- **Wound Management Formulary** this has been updated taking into consideration the most costeffective options for both primary and secondary care

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Code of Practice

This has been removed from the clinical guidance webpage.

The FV Area Drug & Therapeutics Committee (ADTC) has endorsed the Royal Pharmaceutical Society (RPS) overarching principles as appliable across all our sectors of our organisation. Please note that the ADTC will be refreshing this over the next 12 months for local adaptation.

For guidance on the Safe and Secure Handling of Medicines for NHS Forth Valley (FV) please click the link below. Royal Pharmaceutical Society Guidance on Safe and Secure Handling of Medicines

If you require any further guidance around a specific issue – please contact your local pharmacy staff contact for further information

Freestyle Libre® 2: Information sheet to aid staff with switch

Freestyle Libre® sensors are being discontinued by 31/12/2022

Patients need to be switched to Freestyle Libre[®] 2 and advised of change.

Useful information when informing patients of the switch -

How does the FreeStyle Libre® 2 system differ from the FreeStyle Libre ® system?

- 1. **No finger pricks:** There is no need to finger prick when using the FreeStyle Libre® 2 system even when glucose is low, falling or rapidly changing. However, finger pricks are required if glucose readings and alarms do not match symptoms or expectations.
- 2. **More accurate:** The Libre® 2 sensor is more accurate
- 3. Optional alarms: There are three alarms: low glucose, high glucose and signal loss.

Device for monitoring blood glucose: mobile phone App or Reader

When making the switch on EMIS the below Scriptswitch message comes up concerning how to obtain the appropriate App or Reader, whichever is the patient's preferred device:

- · If using a smartphone for monitoring, practices need only change prescription to Freestyle Libre® 2 sensors. Users need to ensure their LibreLink App (LibreLinkUp) has the latest update to use Libre® 2.
- If using the meter, then the patient should visit https://www.freestylelibre.co.uk/replacement to complete the questionnaire at the bottom of the page to be sent a Libre [®]2 Meter before the sensors are changed. Alternatively, they can phone Abbott Customer Care line on 0800 170 1177.

How to activate the alarm function

- · Patients on Freestyle Libre® 2 are not able to receive alarms on multiple devices
- · Patients need to choose on which device they want to receive alarms, either the FreeStyle Libre® 2 reader or a mobile phone with the FreeStyle LibreLink App*
- To receive alarms, the FreeStyle Libre® 2 sensor must be started with the device the patient wants to receive alarms and with the alarm option turned on (alarms are off by default).
- For patients who use the App on their mobile phone to scan the sensors they do not need to download a new App if they are using the latest version (2.5) to enable additional functionality, including the alarms.

Avoid waste

In order to avoid waste, advise the patient to use any existing sensors they have prior to starting the updated product.

*The FreeStyle LibreLink App is only compatible with certain mobile devices and operating systems. If the patient is unsure if their phone is compatible, direct them to the website for more information about device compatibility. www.FreeStyleLibre.co.uk

Process Flowchart (Appendix 1)

NHS FORTH VALLEY PRESCRIBING OF NEW MEDICINES FLOWCHART

This flowchart outlines the NHS Forth Valley process for the prescribing of new medicines. This follows guidance from the Scottish Government for the managed introduction and availability of newly licensed medicines in NHS Scotland

