PROTECTIVE MARKING: NONE

NHS GRAMPIAN Minute of Formulary Group Meeting Tuesday 17 June 2025 at 14:30 via Microsoft Teams

PRESENT APOLOGIES APPROVED

Ms L Cameron Dr D Culligan

Dr V Chieng Mrs M Galvin (and deputy Mrs S Howlett)

Ms A Davie Mrs G McKerron

Ms F Doney Dr L Elliot (Chair) Mrs E Milne

Mrs S O'Beirne Mr M Paterson

Dr K Simpson Mr R Sivewright

IN ATTENDANCE

Mrs Christine Standen, Formulary and Medicines Management Pharmacist.

ITEM SUBJECT ACTION

WELCOME

The Chair welcomed members, opened the meeting, and confirmed that a quorum was present.

1. APOLOGIES

Apologies for absence were requested and noted.

2. MINUTE AND DECISIONS

2.1. Draft minute of the meeting held 20 May 2025

Members accepted the draft note of the meeting subject to minor typographical changes.

The corrected final approved minute will be in the public domain within 21 days of final approval.

FD

2.2. FORMULARY GROUP DECISIONS MAY 2025 - PUBLISHED 02/06/2025

Members ratified the decisions of the May 2025 meeting as published.

3. MATTERS ARISING

3.1. ACTION LOG

The Action log was noted.

3.2. FG1SMC 2655 – ETRASIMOD (MODERATE TO SEVERELY ACTIVE ULCERATIVE COLITIS)

There were no declarations of interest recorded in relation to this product.

The Service responded to the queries from the review for etrasimod for the treatment of patients 16 years of age and older with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy, or a biological agent.

It was confirmed that:

- processes for pre-treatment assessments, first-dose/dose titration and extended monitoring for some patients are still being reviewed
- how often people are seen in clinic depends on UC symptoms, disease state and the

patient, but it could be every three or six months or urgent review

- it is envisaged that Primary Care will monitor patients' BP who have no pre-existing cardiac conditions
- the service would suggest ozanimod is removed from the formulary leaving etrasimod as the only sphingosine-1-phosphate (S1P) receptor modulator available for ulcerative colitis

The Group discussed the proposed blood pressure monitoring arrangements for medicine initiated in secondary care. It was agreed that monitoring by general practice is inappropriate, even for patients with hypertension, due to the administrative burden and lack of a clear framework for timely communication between primary and secondary care. Members confirmed that BP monitoring should be managed by the Homecare services or secondary care hubs.

In the absence of a defined mechanism for timely monitoring and reporting, the Group did not support formulary inclusion until assurance is provided that responsibility will not fall to primary care.

FTEAM

3.3. FG1SMC 2611 - DARIDOREXANT (CHRONIC INSOMNIA)

Item deferred.

4. DISCUSSION - DRAFT FORMULARY GROUP ANNUAL REPORT 2024/25

Members noted the content of the draft Formulary Group annual report for 2024/25.

The Chair requests members review the report and feedback any comments by the 20th June.

ALL

5. New product requests

5.1. FG1SMC 2678 – RELUGOLIX (ADVANCED PROSTATE CANCER)

There were no declarations of interest recorded in relation to this product.

The Group considered the request for relugolix for the treatment of groups of adults with hormone-sensitive/hormone dependent prostate cancer.

The Group noted that:

- relugolix blocks the effects of gonadotrophin-releasing hormone (GnRH) which
 reduces the amount of testosterone in the body and slows down the growth of the
 prostate cancer cells
- the current treatments available include gonadotropin-releasing hormone (GnRH) agonists (leuprorelin, triptorelin and goserelin) and the GnRH antagonist (degarelix)
- the GnRH agonists are associated with an initial rise in testosterone levels which can lead to a flare in symptoms. This flare is not experienced by patients treated with GnRH antagonists.
- relugolix should be initiated with a loading dose of 360mg (three tablets) on the first day, followed by a 120mg (one tablet) dose taken once daily at approximately the same time each day
- relugolix offers the advantage of being an oral medicine compared to the alternatives which are administered by intramuscular or subcutaneous injection
- · evidence comes from:
 - the HERO study which compared relugolix and leuprorelin. The primary outcome
 of sustained castration rate was achieved by 97% of patients in the relugolix group
 and 89% of patients in the leuprorelin group.
 - C27003, a supportive study compared relugolix and degarelix. The primary outcome of effective castration rate was achieved by 95% of patients in the

relugolix group and 89% of patients in the degarelix group.

- patient numbers are expected to be moderate, with supply from primary care on the recommendation of secondary care
- the service stated that relugolix will be an oral alternative to the GnRH antagonist degarelix and the GnRH agonist leuprorelin
- cost offset is available from displacement of the alternative parenteral agents, and relugolix will not incur additional costs including nurse time for administration of parenteral therapies or enhances service payments

The Group acknowledged the advantage of an oral treatment option and accepted the restricted local need for relugolix as an additional GnRH antagonist for the treatment of some groups of patients with prostate cancer, as outlined in SMC 2678.

SMC 2678 - Relugolix 120mg film-coated tablets (Orgovyx®)▼ is routinely available in line with national guidance (SMC 2678). Indications under review:

- · for the treatment of adults with advanced hormone-sensitive prostate cancer
- for the treatment of high-risk localised and locally advanced hormone dependent prostate cancer in combination with radiotherapy
- as neo-adjuvant treatment prior to radiotherapy in patients with high-risk localised or locally advanced hormone dependent prostate cancer
 In an open-label, randomised phase III study, there was a significantly higher sustained castration rate in patients with advanced hormone-sensitive prostate cancer treated with relugolix compared with a gonadotrophin releasing hormone (GnRH) agonist for 48 weeks.

It was classified 1b - available for restricted use under specialist supervision and 8d - treatment may be initiated in community on the recommendation of a consultant/specialist. Treatment with relugolix should be initiated and supervised by specialist physicians experienced in the medical treatment of prostate cancer.

FTEAM

5.2. FG1SMC 2721 - VAMOROLONE (DUCHENNE MUSCULAR DYSTROPHY)

There were no declarations of interest recorded in relation to this product.

The Group considered the request for vamorolone oral suspension for the treatment of Duchenne muscular dystrophy (DMD) in patients aged 4 years and older.

The Group noted:

- · vamorolone:
 - is a synthetic corticosteroid analogue
 - is available as an oral suspension, that is given at a recommended dose of 6mg/kg once daily in patients weighing less than 40kg, and 240mg (equivalent to 6mL) once daily in patients weighing 40kg and above
- evidence comes from VISION-DMD a randomised double-blind study:
 - patients were randomised to vamorolone, prednisolone or placebo
 - the primary outcome was the change from baseline to week 24 in TTSTAND (time to stand from supine) velocity, for vamorolone 6.0mg/kg/day compared to placebo
 - the least squares mean difference of vamorolone 6mg/kg vs placebo was 0.06 (p=0.002)
- a quantitative difference in the safety profile that appears to be in favour of vamorolone compared with prednisone was the absence of a growth stunting effect for vamorolone
- available data suggests that vamorolone does not adversely affect bone health, or at least to a lesser extent than prednisone
- vamorolone may be easier for parents/carers to administer to a child as it is available as an oral suspension, in contrast to prednisolone and deflazacort which come as soluble tablets

- the service stated that vamorolone will be used as an alternative to conventional steroid therapy, oral prednisolone or oral deflazacort, when there are side effects of concern and it is felt to be clinically beneficial to switch to vamorolone
- patient numbers are expected to be small, with minimal cost offset available.
- the SMC advice takes account of the benefits of a PAS that improves the costeffectiveness of vamorolone. The PAS is not available in Primary Care.

The Group accepted the restricted local need for vamorolone oral suspension for the treatment of DMD in patients aged 4 years and older, as outlined in SMC 2721.

SMC 2721 - Vamorolone 40mg/mL oral suspension (Agamree®)▼ is routinely available in line with national guidance (SMC 2721).

Indication under review: treatment of Duchenne muscular dystrophy (DMD) in patients aged 4 years and older.

In a randomised, double-blind, phase IIb study, treatment with vamorolone resulted in a significant improvement in the change in time to stand from supine (TTSTAND) velocity and change in 6-minute walk test (6MWT) distance between baseline and week 24, compared with placebo.

This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.

It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment with vamorolone should only be initiated by specialist physicians with experience in the management of DMD.

FTEAM

5.3. FG1SMC 2731 - UBLITUXIMAB (RELAPSING-REMITTING MULTIPLE SCLEROSIS)

There were no declarations of interest recorded in relation to this product.

The Group considered the request for ublituximab for the treatment of adults with relapsing-remitting multiple sclerosis (RRMS) with active disease defined by clinical or imaging features.

The Group noted that:

- ublituximab is a monoclonal antibody that has been designed to recognise and attach to CD20 on the surface of B cells
- other anti-CD20 monoclonal antibodies included on the formulary include ocrelizumab and ofatumumab
- ublituximab is administered intravenously as 150mg infusion (first infusion), followed by a 450mg intravenous infusion (second infusion) 2 weeks later. Subsequent doses are administered as a single 450mg intravenous infusion every 24 weeks. The first subsequent dose of 450mg should be administered 24 weeks after the first infusion.
- premedication with a steroid and antihistamine must be administered prior to each infusion to reduce the frequency and severity of infusion related reactions
- evidence comes from the ULTIMATE I and ULTIMATE II studies:
 - the primary outcome was annualised relapse rate (ARR)
 - ublituximab reduced the ARR compared with teriflunomide:
 - ULTIMATE I: 0.076 vs 0.188 (absolute risk reduction 0.11; 59% relative reduction; p<0.0001)
 - ULTIMATE II: 0.091 vs 0.178 (absolute risk reduction 0.09; 49% relative reduction; p=0.002)
- a network meta-analysis showed no statistically significant difference between ublituximab, ofatumumab and ocrelizumab for ARR
- the Service has stated that ublituximab may occasionally be used in preference to ocrelizumab or ofatumumab

- · patient numbers are expected to very small
- · cost-offset will be available from displacement of ocrelizumab or ofatumumab
- the SMC advice take account of the benefits of PASs that improve the costeffectiveness of ublituximab

The Group accepted the restricted local need for ublituximab for the treatment of adults with RRMS with active disease defined by clinical or imaging features, as outlined in SMC 2731.

SMC 2731 – Ublituximab 150mg concentrate for solution for infusion (Briumvi®)▼ is routinely available in line with national guidance (SMC 2731). Indication under review: for the treatment of adults with relapsing-remitting multiple sclerosis (RRMS) with active disease defined by clinical or imaging features.

Ublituximab offers an additional treatment choice in the therapeutic class of anti-CD20 monoclonal antibodies.

This advice applies only in the context of approved NHS Scotland Patient Access Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/ list prices that are equivalent or lower. It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be initiated and supervised by specialised physicians experienced in the diagnosis and treatment of neurological conditions and who have access to appropriate medical support to manage severe reactions such as serious infusion related reactions.

FTEAM

5.4. FG1SMC 2686 - RISANKIZUMAB (MODERATELY TO SEVERELY ACTIVE UC)

There were no declarations of interest recorded in relation to this product.

The Group considered the request for risankizumab for the treatment of adults with moderately to severely active UC who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy.

The Group noted that:

- risankizumab
 - is a monoclonal antibody that is designed to attach to interleukin-23 (IL-23) and block its activity
 - is already included in the formulary for the treatment of patients 16 years and older with moderately to severely active Crohn's disease in line with SMC 2534
 - is administered by intravenous (IV) infusion for the first three induction doses (1,200mg at Week 0, Week 4, and Week 8). Starting at Week 12 and every 8 weeks thereafter, the recommended maintenance dose is based on individual patient presentation:
 - a dose of 180mg administered by subcutaneous injection is recommended for patients with adequate improvement in disease activity after induction
 - a dose of 360mg administered by subcutaneous injection is recommended for patients with inadequate improvement in disease activity after induction
- the Service plans to supply risankizumab via homecare
- the subcutaneous risankizumab is delivered by a single-use on-body injector with a
 prefilled cartridge. The on-body injector contains silver oxide-zinc batteries and
 microchips. The homecare service includes disposal of the pump with the integral
 battery.
- evidence comes from the INSPIRE and COMMAND studies:
 - the primary outcome was clinical remission per adapted Mayo score (aMS) defined as stool frequency subscore (SFS) ≤ 1, and not greater than baseline, RBS = 0, and ES ≤ 1 without evidence of friability) at week 12 or week 52 compared to placebo

- INSPIRE:
 - at week 12, risankizumab induced clinical remission in a significantly greater proportion of patients compared with placebo
 - o placebo 12% vs risankizumab 20%.
- COMMAND:
 - clinical remission at 52 weeks was achieved in a significantly greater proportion of patients in the risankizumab groups compared with placebo
 - o risankizumab 180mg 40%, risankizumab 360mg 38% and placebo 25%
- due to the flat pricing of the 180mg and 360mg solution for injection, a 360mg dose should be administered as 1 x 360mg cartridge rather than 2 x 180mg cartridges
- costs will be cumulative as treatment is lifelong
- cost offset will be available from the displacement of other therapies
- the Service has confirmed that risankizumab will be used if all other treatments have failed and after discussion at the inflammatory bowel disease (IBD) multidisciplinary team (MDT)
- the SMC advice takes account of the benefits of a PAS that improves the costeffectiveness of risankizumab

Members felt that the biologics market for UC was becoming crowded and discussed the need for a local treatment pathway. Mindful of the less frequent maintenance dosing schedule (8 weekly) and that risankizumab is already included on the formulary for Crohn's disease, the Group accepted the restricted local need for risankizumab for the treatment of adults with moderately to severely active ulcerative colitis, as outlined in SMC 2686.

SMC 2686 - Risankizumab 180mg, 360mg solution for injection in cartridge, 600mg concentrate for solution for infusion (Skyrizi®) is routinely available in line with national guidance (SMC 2686).

Indication under review: for the treatment of adults with moderately to severely active ulcerative colitis who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy.

Risankizumab offers an additional treatment choice in the therapeutic class of interleukin inhibitors.

This advice applies only in the context of approved NHS Scotland Patient Access Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/ list prices that are equivalent or lower.

It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Risankizumab is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of conditions for which risankizumab is indicated.

FTEAM

5.5. FG1SMC 2629 - SOMAPACITAN (PAEDIATRIC GROWTH HORMONE DEFICIENCY)

There were no declarations of interest recorded in relation to this product.

The Group considered the requests for somapacitan for the replacement of endogenous growth hormone (GH) in children aged 3 years and above and adolescents with growth failure due to growth hormone deficiency (paediatric GHD).

The Group noted that:

- somapacitan:
 - is also licensed for the replacement of endogenous GH in adults with GHD however the SMC acceptance is restricted to children aged 3 years and above and adolescents
 - is a long-acting recombinant human GH derivative
 - is administered once-weekly via subcutaneous injection, at a recommended starting dose of 0.16mg/kg/week. The dose may be individualised and adjusted

based on growth velocity, adverse reactions, body weight and serum insulin-like growth factor I (IGF-I) concentrations. Patients will be taught how to split doses over two pens to minimise drug wastage.

- the current treatments in NHS Grampian for paediatric GHD include somatropin
- somapacitan has the advantage of weekly administration compared to somatropin which is administered daily
- evidence comes from REAL-4 which compared once weekly somapacitan with daily growth hormone somatropin:
 - the primary end point was annualised height velocity at week 52
 - the observed annualised height velocity increased from baseline to week 52 in a similar manner for both treatment groups; 11.2cm/year with somapacitan versus 11.7cm with daily somatropin
 - non-inferiority of once-weekly somapacitan to once-daily somatropin was confirmed
- the number of new patients starting GH each year is expected to be small, and not all of the patients would be started on somapacitan
- once GH is started treatment will continue until completion of growth, therefore the number of patients on GH treatment will increase year on year
- the service stated that treatment will continue until completion of growth; estimated as 14 years of age for girls and 16 years of age for boys, and patients should be clinically re-evaluated for the need for growth hormone treatment once the epiphyses are fused
- the service stated that somapacitan will be a useful alternative to daily growth hormone injection in children with needle phobia, compliance and other issues with daily delivery of the medication

Members discussed the requested formulary classification of 'treatment to be initiated in community on the recommendation of a consultant/specialist'.

Members accepted that some GH preparations are prescribed in Primary Care, and a long-acting GH is currently classified as 'hospital-only'.

Members who had experience prescribing GH on the advice of the paediatric specialist service confirmed that, from their experience, patients were very well managed [by paediatrics], processes were established, clinic letters were very detailed (dose changes, monitoring etc.), and the specialist nurses regularly engage with patients/carers.

The Formulary Team will invite the specialist service to a future meeting to describe how they work with families and General Practices to manage paediatric GHD (dose changes, monitoring, counselling, education etc).

FTEAM

The Group accepted the restricted local need for somapacitan as an additional longacting GH derivative for the management of paediatric GHD for children with needle phobia, compliance and other issues with daily delivery of GH.

SMC 2629 - Somapacitan 10mg/1.5mL, 15mg/1.5mL solution for injection pre-filled pens (Sogroya®)▼ is routinely available in line with national guidance (SMC 2629). Indication under review: for the replacement of endogenous growth hormone (GH) in children aged 3 years and above, and adolescents with growth failure due to growth hormone deficiency (paediatric GHD).

Somapacitan offers an additional treatment choice in the therapeutic class of recombinant human growth hormones for this indication.

It was classified 1b - available for restricted use under specialist supervision and 8d - treatment may be initiated in community on the recommendation of a consultant/specialist. Somapacitan should be initiated and monitored by physicians who are appropriately qualified and experienced in the diagnosis and management of patients with growth hormone deficiency (e.g. endocrinologists).

FTEAM

5.6. FG1SMC 2642 - EMPAGLIFLOZIN AND FG1SMC 2763 - DAPAGLIFLOZIN (CHRONIC KIDNEY DISEASE)

Mr Paterson declared a personal, non-specific interest in AstraZeneca UK Limited and took part in decision-making.

The Group considered the requests for dapagliflozin and empagliflozin as add-on treatment for chronic kidney disease (CKD).

The Group noted that:

- standard of care for CKD in patients with and without diabetes is represented by blood
 pressure control and reduction of proteinuria through renin-angiotensin-aldosterone
 system (RAAS) blockade (angiotensin converting enzyme inhibitors or angiotensin II
 receptor blockers) combined with cardiovascular disease risk management and/or and
 glycaemic control as necessary
- dapagliflozin and empagliflozin are selective and reversible sodium-glucose cotransporter-2 (SGLT-2) inhibitors
- SGLT-2 inhibitors block glucose reabsorption in the kidneys and the glucose-lowering effect is less pronounced at lower eGFR levels
- SGLT-2 inhibitors act as a diuretic increasing the elimination of salt and water in the
 urine, decreasing the overall blood volume, reducing the effort needed for the heart to
 pump blood, thereby improving its function in patients with heart failure
- blocking the action of SGLT-2 supports heart function in patients with heart failure and kidney function in patients with chronic kidney disease, regardless of having diabetes, and these benefits are thought to be independent of glycaemic control
- dapagliflozin was the first SLGT-2 inhibitor approved for use in NHS Scotland for the treatment of chronic kidney disease
- evidence for dapagliflozin and empagliflozin shows that both are superior to placebo in preventing the primary composite endpoint:
 - dapagliflozin: ≥50% sustained decline in estimated glomerular filtration rate (eGFR), reaching end-stage kidney disease (ESKD), cardiovascular or renal death (HR 0.61 [95% CI 0.51, 0.72]; p < 0.0001)
 - empagliflozin: the first occurrence of progression of kidney disease or death from cardiovascular causes. Progression of kidney disease was defined as the first occurrence of any of the following; ESKD, sustained decline in eGFR to <10 mL/min/1.73m², death from renal causes, sustained decline of ≥40% in eGFR from randomisation (HR 0.72 [95% CI 0.64, 0.82]; p < 0.001).
- a 28-tablet pack of dapagliflozin or empagliflozin 10mg tablets (equivalent to 28 days treatment) costs £36.59 (£43.91 inc. VAT), equivalent to a cost per patient per annum of £477.30 [£572.76 inc. VAT]
- this will be a new additional cost, as SGLT-2 inhibitors will be added to maximum tolerated renin-angiotensin-aldosterone system (RAAS) therapies. Costs will be cumulative as this will be a long-term treatment.
- the request seeks to include the two SGLT-2 inhibitors on the formulary for a wider group of adults with CKD (with and without diabetes) than currently accepted for dapagliflozin
- patent challenges to dapagliflozin means there is a potential that generic versions of dapagliflozin will be available earlier than previously anticipated

The Group accepted the restricted local need for dapagliflozin and empagliflozin as addon treatment for the management of chronic kidney disease. Members supported including dapagliflozin as the first-choice SGLT-2 inhibitor.

SMC 2763 - Dapagliflozin 5mg, 10mg film-coated tablets (Forxiga®) is routinely available in line with national guidance (SMC 2763).

Indication under review: for the treatment of chronic kidney disease in adults having individually optimised standard care (including angiotensin converting

enzyme inhibitors or angiotensin II receptor blockers, unless these are contraindicated or not tolerated), and either, at the start of treatment:

- an estimated glomerular filtration rate (eGFR) of 20mL/min/1.73m² up to 45mL/min/1.73m², or
- an eGFR of 45mL/min/1.73m² up to 90mL/min/1.73m² and either:
 - a urine albumin-to-creatinine ratio (uACR) of 22.6 mg/mmol or more, or
 - Type 2 Diabetes Mellitus (T2DM)

Restriction: start treatment on the advice of a Renal Consultant/Physician. It was classified 1b - available for restricted use under specialist supervision and 8d - treatment may be initiated in community on the recommendation of a consultant/specialist.

FTEAM

SMC 2642 - Empagliflozin 10mg film-coated tablets (Jardiance®) is routinely available in line with local guidance.

Indication under review: as a second-choice SGLT-2 inhibitor for the treatment of chronic kidney disease in adults having individually optimised standard care (including angiotensin converting enzyme inhibitors or angiotensin II receptor blockers, unless these are contraindicated or not tolerated), and either, at the start of treatment:

- an estimated glomerular filtration rate (eGFR) of 20mL/min/1.73m² up to 45mL/min/1.73m², or
- an eGFR of 45mL/min/1.73m² up to 90mL/min/1.73m² and either:
 - a urine albumin-to-creatinine ratio (uACR) of 22.6 mg/mmol or more, or
 - Type 2 Diabetes Mellitus (T2DM)

Restriction: start treatment on the advice of a Renal Consultant/Physician. It was classified 1b - available for restricted use under specialist supervision and 8d - treatment may be initiated in community on the recommendation of a consultant/specialist.

FTEAM

6. FORMULARY REVIEW

6.1. FORMULARY UPDATES JUNE 2025

There were no declarations of interest recorded in relation to this product.

DISCONTINUATIONS

Ms Doney reported that:

- Teva UK Limited has discontinued Airomir[®] 100micrograms/dose inhaler (salbutamol pressurised metered dose inhaler (pMDI)). Alternative salbutamol pMDIs are available, with Salamol[®] the preferred product due to its lower carbon footprint.
- Vifor Fresenius Medical Care Renal Pharma UK Ltd has discontinued the nonformulary medicine Osvaren® 435mg/235mg film-coated tablets (calcium acetate/magnesium carbonate heavy)
- Novartis Pharmaceuticals UK Ltd has discontinued Sandimmun[®] 25mg, 50mg, 100mg capsules, 100mg/mL oral solution (ciclosporin), discontinuation is a commercial decision. Neoral[®] is the preferred brand of ciclosporin for solid organ transplant.

The discontinuations are considered low impact discontinuations.

Members supported update of the formulary entries to note the discontinuations.

UNCONTROLLED WHEN PRINTED PROTECTIVE MARKING: NONE

FTEAM

7. PUBLISHED ADVICE

7.1. SCOTTISH MEDICINES CONSORTIUM ADVICE PUBLISHED JUNE 2025

The Group noted the SMC advice published June 2025.

Following publication of the negative SMC recommendations, for durvalumab (Imfinzi®) SMC 2735 and Suvexx® (sumatriptan/naproxen) SMC 2756, and the non-submission statements, for bempedoic acid (Nilemdo®) SMC 2740, Nustendi® (bempedoic acid/ezetimibe) SMC 2741, pegylated liposomal irinotecan (Onivyde®) SMC 2812 and pegzilarginase (Loargys®) ▼ SMC 2813, these medicines will not be included on the Grampian Joint Formulary for the indications in question.

The following SMC accepted medicines have not been processed within a 60-day timescale:

- SMC 2744 bevacizumab gamma (Lytenava®)▼ (submission expected)
- SMC 2751 cladribine (Mavenclad®) (submission expected)
- SMC 2750 ruxolitinib (Jakavi®)
- SMC 2732 selpercatinib (Retsevmo[®])▼

Local advice for these medicines and indications will be included in the June 2025 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'.

FTEAM

8. PROVISIONAL ADVICE

8.1. SCOTTISH MEDICINES CONSORTIUM ADVICE ISSUED JUNE 2025

The Group noted the SMC provisional advice issued June 2025.

If the negative SMC recommendations are published next month, these medicines will not be included on the formulary for the indications in question.

FTEAM

9. OTHER BUSINESS

9.1. CMO LETTER: UK GOVERNMENT RESTRICTIONS ON THE USE OF PUBERTY SUPPRESSING HORMONES (PUBERTY BLOCKERS); ADDITIONAL INFORMATION FOR PRESCRIBERS AND PHARMACISTS/DISPENSING DOCTORS

The Chair highlighted the CMO letter regarding the statutory changes that the UK Government has implemented regarding restrictions on the use of puberty suppressing hormones (puberty blockers).

10. DOCUMENTS FOR INFORMATION

Items 10.1 (Medicines and Healthcare products Regulatory Agency (MHRA) Safety Roundup May 2025), 10.2 (MHRA Drug Safety Update 10 June 2025 (Valproate), 10.3 (Medicine Guidelines and Policies Group meeting minute January 2025), and 10.4 (Grampian Primary Care Prescribing Group meeting minute March 2025) were noted.

11. AOCB

MHRA: GLP-1 MEDICINES FOR WEIGHT LOSS AND DIABETES: WHAT YOU NEED TO KNOW The Chair highlighted guidance, issued by the Medicines and Healthcare products Regulatory Agency (MHRA), on the safe and effective use of glucagon-like peptide-1 receptor agonists (GLP-1s or GLP-1RAs) for weight loss and diabetes. The link was issued on email to members and will be linked to the formulary website. Guidance

PROTECTIVE MARKING: NONE

ITEM SUBJECT ACTION

THANK YOU AND AU REVOIR

The Chair reported that this was Ms Davie last meeting for a year.

The Chair formally thanked Ms Davie for her valuable contributions and dedication during her time on the Group. Her expertise and commitment has been greatly appreciated. Members wished her every success as she embarks on a secondment opportunity, and look forward to welcoming her back in the future.

SUMMER BREAK

CHAIR'S SIGNATURE

The Chair reminded members that there is not a meeting in July, and wished everyone a good summer break.

DATE OF NEXT MEETING

Tuesday 19 August 2025 starting at 14.30 via Microsoft Teams.

Signature on file	
Dr Louise Elliot	DATE 19 August 202