NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 19 August 2025 at 14:30 via Microsoft Teams

PRESENT	APOLOGIES	APPROVED
Ms L Cameron (from item 5.1)	Dr D Culligan	
Dr V Chieng	Mrs M Galvin (and deputy Mrs S Howlett)	
Ms F Doney	Mr M Paterson	
Dr L Elliot (Chair)	Dr K Simpson	
Mrs G McKerron (from item 5.2)	Mr R Sivewright	
Mrs E Milne		
Mrs S O'Beirne (from item 6.4)		

IN ATTENDANCE
Mrs Christine Standen, Formulary and Medicines Management Pharmacist.

OBSERVERS
Ms Ellen Bruce, Primary Care Clinical Pharmacist, Aberdeen City Health and Social Care Partnership.
Mr Yousef Al-Obaidi, Advanced Clinical Primary Care Pharmacist, Aberdeen City Health and Social Care Partnership.

Note: At the scheduled start time, the Chair confirmed that the meeting was not quorate. Business transacted during this period was noted. Once quorum was achieved, the Chair reviewed the earlier decisions, and all relevant items were formally ratified in accordance with governance procedures.

ITEM	SUBJECT	ACTION
	WELCOME The Chair welcomed members, formally opened the meeting, and facilitated introductions for those attending as observers. Ms Ellen Bruce and Mr Yousef Al-Obaidi attended the meeting as observers, with a view to joining as the interim pharmacy representative for Aberdeen City Health and Social Care Partnership.	
1.	**APOLOGIES** Apologies for absence were requested and noted.	
2.	**MINUTE AND DECISIONS**	
	2.1. DRAFT MINUTE OF THE MEETING HELD 17 JUNE 2025 Members accepted the draft note of the meeting, subject to minor typographical amendments. The final approved minute will be published in the public domain within 21 days of its formal approval.	**FD**
	2.2. FORMULARY GROUP DECISIONS JUNE 2025 - PUBLISHED 02/06/2025 Members formally ratified the June 2025 decisions document 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) Item deferred.	

ITEM	SUBJECT	ACTION

4. DISCUSSION

None.

5. NEW PRODUCT REQUESTS

5.1. FG1SMC 2714 – ELAFIBRANOR (PRIMARY BILIARY CHOLANGITIS)

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

The Group considered the request for elafibranor for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA.

The Group noted that:

- elafibranor:
  - is the first peroxisome proliferator-activated receptor (PPAR) alpha and delta agonist to be licensed in the UK
  - offers an additional licensed second-line treatment option for PBC [in addition to obeticholic acid]
  - is taken at a recommended dose of 80mg once daily
- evidence comes from the ELATIVE study:
  - at week 52, significantly more patients achieved a cholestasis response in the elafibranor group compared with the placebo group (51% versus 3.8%)
  - during the study period, 95% of patients received concomitant ursodeoxycholic acid
  - an indirect treatment comparison comparing elafibranor and obeticholic acid showed that elafibranor demonstrated favourable results for improving liver function biomarkers, reducing pruritus over 52 weeks and patients treated with elafibranor were less likely to discontinue treatment due to pruritus or any cause compared with obeticholic acid
- the service plans to:
  - supply elafibranor by a homecare arrangement so costs will not include VAT
  - use elafibranor if obeticholic acid proves ineffective or is associated with adverse drug reactions. In certain clinical scenarios - such as where a marked reduction in liver function markers (alkaline phosphatase, bilirubin, and gamma-glutamyl transferase) is required, or in cases of severe pruritus - elafibranor may be considered prior to initiating obeticholic acid
- some costs are already in the system as patients have accessed elafibranor via individual patient requests
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of elafibranor

The Group accepted the restricted local need for elafibranor as an additional treatment option for PBC in adults with an inadequate response or unable to tolerate UDCA, as outlined in SMC 2714.

SMC 2714 - Elafibranor 80mg film-coated tablets (Iqirvo®)▼ is routinely available in line with national guidance (SMC 2714).
Indication under review: for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA.
In a randomised, double-blind, phase III study, there was a significantly higher cholestasis response at 52 weeks to elafibranor compared with placebo in patients with primary biliary cholangitis who have had an inadequate response or intolerance to UDCA.
This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon

ITEM	SUBJECT	ACTION

which the decision was based, or a PAS/list price that is equivalent or lower. It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. **FTEAM**

5.2. FG1SMC 2719 - CEMIPLIMAB (RECURRENT OR METASTATIC CERVICAL CANCER)

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

The Group considered the request for cemiplimab as monotherapy for the treatment of adults with recurrent or metastatic cervical cancer and disease progression on or after platinum-based chemotherapy.

The Group noted:

- cemiplimab:
  - [for this indication] meets SMC end of life and orphan equivalent criteria
  - [for this indication] was accepted for use in NHS Scotland only in the context of the SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios and the output from the PACE process
  - is a fully humanised immunoglobulin G4 (IgG4) monoclonal antibody that increases T cell responses including anti-tumour responses by binding to the programmed cell death-1 (PD-1) receptor and blocking its interaction with its ligands PD-L1 and PD-L2
  - is administered as an intravenous infusion over 30 minutes, at a recommended dose of 350mg every 3 weeks
  - was accepted for use in NHS Scotland following a full submission assessed under the end of life and orphan equivalent medicine process
- the service has experience using cemiplimab as it is already included on formulary for the treatment of cutaneous squamous cell carcinoma
- evidences comes from EMPOWER-Cervical 1:
  - cemiplimab treatment resulted in a statistically significant improvement in overall survival (OS) compared with investigator's choice chemotherapy; a median survival gain of approximately 3 months is considered clinically relevant for this patient population
  - the OS in the squamous cell carcinoma (SCC) population was 11.1 months vs 8.8 months
  - the median OS in the total population was 12 months and 8.5 months
  - an exploratory subgroup analysis based on PD-L1 status suggested that efficacy improved with increasing PD-L1 expression and there was uncertainty regarding the benefit in PD-L1 <1% given this represented only 15% (92/608) of patients in the total population. However, the regulatory authority considered there to be clinical benefit in this underpowered subgroup [ref SMC]. The service plans to use cemiplimab second-line in patients who are PD-L1 negative.
  - only included patients with an Eastern Cooperative Oncology Group Performance Status (ECOG PS) of 0 or 1
- in the study treatment continued up to 96 weeks or until disease progression or unacceptable toxicity; the median duration of treatment was 15.2 weeks
- patient numbers are expected to be very small, with minimal offset available
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of cemiplimab

The Group accepted the restricted local need for cemiplimab as monotherapy for the treatment of adults with recurrent or metastatic cervical cancer and disease progression on or after platinum-based chemotherapy.

SMC 2719 – Cemiplimab 350mg concentrate for solution for infusion (Libtayo®)▼ is routinely available in line with national guidance (SMC 2719).
Indication under review: as monotherapy for the treatment of adults with recurrent

ITEM	SUBJECT	ACTION

or metastatic cervical cancer and disease progression on or after platinum-based chemotherapy.
In a phase III study, cemiplimab monotherapy resulted in a significant improvement in overall survival, compared with investigator's choice of chemotherapy.
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 must be initiated and supervised by physicians experienced in the treatment of cancer. **FTEAM**

5.3. FG1SMC 2664 - IVOSIDENIB (LOCALLY ADVANCED OR METASTATIC CHOLANGIOCARCINOMA)

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

The Group considered the request for ivosidenib as monotherapy for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with an isocitrate dehydrogenase-1 (IDH1) R132 mutation who were previously treated by at least one prior line of systemic therapy.

The Group noted that:

- ivosidenib:
  - is an inhibitor of mutant IDH1 enzyme. The mutant IDH1 enzyme converts alpha-ketoglutarate to 2-hydroxyglutarate (2-HG), which impairs cellular differentiation and promotes tumour formation.
  - [for this indication] meets SMC end of life and orphan criteria
  - [for this indication] was accepted for use in NHS Scotland only in the context of the SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios and the output from the PACE process
- IDH1 R132 mutation testing is available and conducted mostly at diagnosis
- the recommended dose is 500mg ivosidenib (2 x 250mg tablets) taken orally once daily
- an ECG must be performed prior to treatment initiation, at least weekly during the first 3 weeks of therapy and then monthly thereafter if the QTc interval remains ≤480 msec due to the risk of QT prolongation. The service will assume responsibility for the required monitoring and intends to coordinate this as part of outpatient care.
- the service advised that pemigatinib is an available treatment option for this patient group, specifically for individuals with fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement who have progressed following at least one prior line of systemic therapy. Ivosidenib is indicated only for patients with an IDH1 R132 mutation, and it was noted that patients would not present with both mutations.
- evidence comes from the ClarIDHy study:
  - the primary outcome was progression-free survival (PFS) assessed by independent radiology centre per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1
  - the median PFS was 2.7 months versus 1.4 months for ivosidenib versus placebo respectively
  - the median duration of ivosidenib treatment in the ClarIDHy study was 2.8 months (range 0.1 months to 45.1 months)
- the submitting company presented SMC with an indirect treatment comparison of ivosidenib versus FOLFOX:
  - OS: ivosidenib versus FOLFOX, the hazard ratio suggested possible benefit in the analysis that was adjusted for crossover, despite the statistical testing of this result not being not definitive

  - PFS: ivosidenib versus FOLFOX, comparison of curves with median 2.7 versus 4.0 months
- patient numbers are expected to be very small
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of ivosidenib
- the service has stated that treatment will be an alternative to standard chemotherapy with FOLFOX (oxaliplatin/fluorouracil); ivosidenib should be better tolerated and it is an oral therapy
- minimal cost offset will be available based on drug costs however as ivosidenib is an oral tablet, there will be reduced costs for nurse/chair time as FOLFOX is administered intravenously
- the service confirmed that treatment with ivosidenib may be considered as an alternative to standard chemotherapy with FOLFOX (oxaliplatin/fluorouracil), noting that ivosidenib is an oral therapy and is expected to be better tolerated
- while minimal cost offset is anticipated based on drug acquisition costs, the use of an oral formulation is expected to reduce associated administration costs, including nurse and chair time, compared to intravenous FOLFOX

The Group discussed the small increase in PFS. Noting the positive SMC advice the Group accepted the restricted local need for ivosidenib as monotherapy for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with an isocitrate dehydrogenase-1 (IDH1) R132 mutation who were previously treated by at least one prior line of systemic therapy.

SMC 2664 – Ivosidenib 250mg tablets (Tibsovo®)▼ is routinely available in line with national guidance (SMC 2664).
Indication under review: as monotherapy for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with an isocitrate dehydrogenase-1 (IDH1) R132 mutation who were previously treated by at least one prior line of systemic therapy.
In a double-blind, phase III study, ivosidenib, compared with placebo, significantly improved progression-free survival in adults with locally advanced or metastatic cholangiocarcinoma with IDH1 mutation who were previously treated by one or two prior lines of systemic therapy for advanced disease.
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 should be initiated under the supervision of physicians experienced in the use of anti-cancer medicinal products. Before taking ivosidenib, patients must have confirmation of an IDH1 R132 mutation using an appropriate diagnostic test. **FTEAM**

5.4. FG1SMC 2754 - CABOZANTINIB (HEPATOCELLULAR CARCINOMA)

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

The Group considered the request for cabozantinib tablets as monotherapy for the treatment of hepatocellular carcinoma (HCC) in adults who have previously been treated with sorafenib.

The Group noted that:
- cabozantinib:
  - is a protein kinase inhibitor that blocks mesenchymal epithelial transition factor (MET), vascular endothelial growth factor (VEGF) receptors and other tyrosine

kinases including the GAS6 receptor (AXL)
  - is taken at a recommended dose of 60mg once daily. Treatment should continue until the patient is no longer clinically benefiting from therapy or until unacceptable toxicity occurs.
  - is already included on NHS Grampian formulary for the treatment of advanced renal cell carcinoma
- cabozantinib is available in both tablet and capsules formulations; these are not bioequivalent and should not be used interchangeably
- evidence comes from the CELESTIAL trial which demonstrated a statistically significant OS benefit with cabozantinib compared with placebo, with a median OS of 10.2 months versus 8.0 months
- in the CELESTIAL trial the median duration of treatment for the cabozantinib group was 3.8 months
- patient numbers are expected to be very small
- cabozantinib will be offered as an alternative to regorafenib in patients previously treated with sorafenib
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of cabozantinib tablets

The Group accepted the restricted local need for cabozantinib tablets as an additional protein kinase inhibitor for the treatment of HCC in adults who have previously received sorafenib, as outlined in SMC 2754.

SMC 2754 – Cabozantinib 20mg, 40mg, 60mg film-coated tablets (Cabozantinib Ipsen) is routinely available in line with national guidance (SMC 2754).
Indication under review: as monotherapy for the treatment of hepatocellular carcinoma (HCC) in adults who have previously been treated with sorafenib.
Cabozantinib offers an additional treatment choice in the therapeutic class of protein kinase inhibitors.
Another protein kinase inhibitor was accepted for use under the end of life process.
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.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Therapy should be initiated by a physician experienced in the administration of anticancer medicinal products. **FTEAM**

5.5. METASTATIC RESISTANT PROSTATE CANCER (MCRPC) - FG1SMC 2617 - OLAPARIB AND FG1SMC 2753 - TALAZOPARIB

There were no declarations of interest recorded in relation to these products.

The Group considered the requests for two medicines, olaparib and talazoparib, for the treatment of adults with metastatic castration resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated.
Olaparib is taken in combination with abiraterone and prednisone or prednisolone, whereas talazoparib is taken in combination with enzalutamide.

The Group noted that:
- olaparib and talazoparib are inhibitors of human poly (ADP-ribose) polymerase enzymes, which have been shown to inhibit the growth of selected tumour cells
- olaparib meets SMC end of life and orphan equivalent criteria for this indication
- olaparib was accepted for use in NHS Scotland following a full submission, assessed under the end of life and orphan equivalent medicine process, only in the context of the SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios and the output from the PACE process

- talazoparib was accepted for use in NHS Scotland following an abbreviated submission that documented 'Another medicine combination within this therapeutic class has been accepted under the end of life and orphan equivalent process for this indication'
- medicines reviewed under the abbreviated submissions process are estimated to have a limited net budget impact and resource allocation across NHS Scotland
- olaparib is administered at a dose of 300mg (two 150mg tablets) twice daily in combination with abiraterone 1,000mg twice daily and prednisone or prednisolone
- talazoparib is administered as 0.5mg (two 0.25mg capsules) daily in combination with enzalutamide 160mg (four 40mg tablets)
- olaparib is already included on formulary for multiple indications
- evidence for olaparib comes from PROpel:
  - the median radiographic PFS was 25 months versus 16.5 months for the olaparib group versus the placebo group respectively
  - the treatment effect for radiographic PFS was also larger in patients with a BRCA mutation (n=85; HR 0.23 [95% CI 0.12 to 0.43]) compared with those without (n=693; HR 0.76 [95% CI 0.61 to 0.94])
  - the median duration of treatment in the olaparib group was 18.5 months
- evidence for talazoparib comes from TALAPRO-2
  - the median radiographic PFS was not reached in the talazoparib group versus 21.9 months in the placebo group
  - the median duration of talazoparib exposure was 86 weeks (~20 months) (range 0.29 to 186.14)
- there are no direct evidence comparing olaparib plus abiraterone plus prednisolone and talazoparib plus enzalutamide. A network meta-analysis suggested that the two combinations had comparable efficacy.
- patient numbers are expected to be very small
- the SMC advice, for both olaparib and talazoparib, takes account of the benefits of a PAS that improves the cost-effectiveness of treatment
- the patent for enzalutamide is expected to expire in the next few years
- the service confirmed that treatment benefit is greatest in patients with confirmed BRCA1 or BRCA2 mutations. However, in cases where BRCA status is unknown and access is requested, both the product licence and the SMC advice permit use.
- the service confirmed that olaparib will be used for mCRPC in patients with BRCA1/2-mutations (germline and/or somatic) when chemotherapy is not clinically indicated, and who have not received prior abiraterone treatment. Talazoparib will provide an alternative option in this patient group, for example where steroid-sparing treatment is advantageous.
- this will be a new cost to the system as olaparib and talazoparib are added to current treatments, abiraterone plus prednisolone or enzalutamide respectively. The length of treatment with abiraterone (plus prednisolone) or enzalutamide is likely to increase.

The Group accepted the restricted local need for olaparib and talazoparib, for the treatment of adults with mCRPC in whom chemotherapy is not clinically indicated, as outlined in SMC 2617 and SMC 2753 respectively.

SMC 2617 - Olaparib 100mg, 150mg film-coated tablets (Lynparza®) is routinely available in line with national guidance (SMC 2617)
Indication under review: in combination with abiraterone and prednisone or prednisolone for the treatment of adults with metastatic castration resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated.
In a phase III study, radiographic progression-free survival was significantly improved with the addition of olaparib to abiraterone plus prednisone or prednisolone compared with the addition of placebo in patients with mCRPC who had received no previous systemic therapy for metastatic disease.
This advice applies only in the context of approved NHS Scotland Patient Access

ITEM	SUBJECT	ACTION

Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/list prices that are 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 olaparib should be initiated and supervised by a physician experienced in the use of anticancer medicinal products. **FTEAM**

SMC 2753 - Talazoparib 0.1mg, 0.25mg, 1mg hard capsules (Talzenna®) is routinely available in line with national guidance (SMC 2753)
Indication under review: in combination with enzalutamide for the treatment of adults with metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated.
Talazoparib offers an additional treatment choice in the therapeutic class of poly ADP-ribose polymerase inhibitors given in combination with a hormonal agent for this indication.
Another medicine combination within this therapeutic class has been accepted under the end of life and orphan equivalent process for this indication.
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 with talazoparib should be initiated and supervised by a physician experienced in the use of anticancer medicinal products. **FTEAM**

6. FORMULARY REVIEW

6.1. FORMULARY UPDATES AUGUST 2025

There were no declarations of interest recorded in relation to these products.

ULTRA-ORPHAN PATHWAY MEDICINE

Ms Doney reported that the Scottish Government has confirmed that from 19 June 2025, exagamglogene autotemcel (exa-cel) (Casgevy®)▼ can be prescribed within the ultra-orphan pathway while further evidence on its effectiveness is generated. Following the period of data collection the company will provide an updated submission for reassessment to allow a decision on its routine use in NHS Scotland.

In line with local processes the Formulary Group supported updating the current decision to confirm that exagamglogene autotemcel (exa-cel) can be prescribed within the ultra-orphan pathway.

UMAR SMC 2709 - Exagamglogene autotemcel 4-13 x 10^6 cells/mL dispersion for infusion (Casgevy®)▼ is not routinely available in NHS Grampian.
Indication under review: for the treatment of transfusion-dependent beta-thalassemia in patients 12 years of age and older for whom haematopoietic stem cell transplantation is appropriate and a human leukocyte antigen matched related haematopoietic stem cell donor is not available.
Not routinely available in NHS Grampian. If local need identified treatment is available through the National Services Scotland Ultra orphan medicines Risk Share Scheme. **FTEAM**

DEBRANDING

Ms Doney reported that Eisai Ltd has debranded Fycompa®, which will now be marketed

as perampanel Eisai®. The PAS agreement has been updated to reflect this change in branding. The patent for perampanel is expected to expire in 2026, at which point generic versions are anticipated to enter the market.

Members supported updating the formulary entry to remove the brand name, only the generic name (perampanel) will be noted on the formulary. **FTEAM**

DISCONTINUATIONS

Ms Doney reported that:

- Teva UK Limited has discontinued Airomir® Autohaler® 100micrograms/dose inhaler (salbutamol pressurised metered dose inhaler (pMDI)). Alternative breath-activated pMDIs are available.
- Eli Lilly and Company Limited has ceased marketing and supply of Strattera® oral solution. A generic atomoxetine 4mg/1mL oral solution is expected to be available later this year.
- Neon Healthcare Ltd has confirmed that buserelin nasal spray, as the brand Suprecur®, has not been marketed for a number of years and the company does not have a timeline for when it will be supplied again
- Accord Healthcare Limited has confirmed that manufacturing of hydrocortisone 2.5mg muco-adhesive buccal tablets was discontinued in June and stocks are now depleted
- Wockhardt UK Ltd has discontinued three porcine insulin suspension vials – Hypurin® porcine isophane 100units/mL, Hypurin® porcine neutral 100units/mL and Hypurin® porcine 30/70 Mix 100units/mL. The discontinuation is a commercial decision. Patient numbers are small, and patients will be identified at general practice level.

The changes are considered low impact discontinuations.

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

6.2. ANTIBIOTICS FOR THE TREATMENT OF ACNE

Members reviewed the requested changes to the current oral antibiotics for acne.

The changes bring the formulary in line with the local antimicrobial prescribing recommendations (National Institute for Health and Care Excellence (NICE) guideline NG198 Acne vulgaris: management). The changes are proposed by the Specialist Antibiotic Pharmacists and supported by the Antimicrobial Management Team (AMT).

The Group noted that:

- oral antibiotics are not used as monotherapy, but as an adjunct to (non-antibiotic) topical treatments for moderate to severe acne
- for adults and adolescents 12 years and older the first-line tetracycline options are:
  - lymecycline 408mg and
  - doxycycline immediate-release. The 100mg dose is noted in guidelines for the treatment of acne vulgaris but is an unlicensed dose.
- trimethoprim (300mg twice daily) is a ‘weak’ recommendation from NICE based on the committee’s experience, but mindful of the Medicines and Healthcare products Regulatory Agency (MHRA) requirement that oral isotretinoin should only be prescribed for severe forms of acne that are resistant to adequate courses of standard therapy with systemic antibacterials and topical therapy. Trimethoprim used as an adjunct for moderate to severe acne in adults is an unlicensed indication.
- oxytetracycline and tetracycline remain on the formulary, but are not first-line choices
- erythromycin remains on the formulary for use if tetracyclines are contraindicated
- minocycline remains non-formulary for acne

The Group supported the updates requested by the AMT. **FTEAM**

ITEM	SUBJECT	ACTION

The Group accepted the restricted local need for the off-label use of trimethoprim tablets as outlined in NG198.

SBAR - Trimethoprim 100mg, 200mg tablets is routinely available in line with local guidance.
Indication under review: [off-label use] as an adjunctive treatment for moderate to severe acne in adults who cannot tolerate or have contraindications to oral lymecycline or oral doxycycline.
It was classified 3b – licensed product available for restricted off-label use and 8e - treatment may be initiated in either Primary or Secondary care. **FTEAM**

6.3. SODIUM-GLUCOSE COTRANSPORTER-2 (SGLT2) INHIBITORS – DAPAGLIFLOZIN GENERICS

There were no declarations of interest recorded in relation to these products.

Ms Doney reported the earlier-than-anticipated availability of generic dapagliflozin following the UK Court of Appeal's decision to uphold the invalidation of AstraZeneca's patent for Forxiga®. Multiple manufacturers are expected to launch generic versions, with market entry anticipated imminently.

The Group noted that:
- three sodium-glucose cotransporter-2 (SGLT2) inhibitors are included on the formulary – canagliflozin, dapagliflozin and empagliflozin
- dapagliflozin is the first agent to come off patent, enabling the introduction of generic alternatives

In preparation for the launch of generic dapagliflozin the Group supported noting dapagliflozin as the first-choice SGLT-2 inhibitor for NHS Grampian.

Dapagliflozin 5mg, 10mg film-coated tablets is routinely available in line with local guidance.
Indication under review: first-choice sodium-glucose cotransporter-2 (SGLT2) inhibitor in line with the current formulary acceptance, including any restrictions.
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**

6.4. RESPIRATORY UPDATES

There were no declarations of interest recorded in relation to these products.

Ms Doney provided an update on the Respiratory Managed Clinical Network (MCN) Prescribing Subgroup. The subgroup is currently undertaking a review of the local prescribing guidance for asthma.

Ms Doney noted that there is increasing generic competition in the market for Fostair® and Luforbec® pressurised metered-dose inhalers (pMDIs). Luforbec® is currently the preferred generic alternative to Fostair® pMDI, however this market is highly dynamic, with several recent price changes.

In response to ongoing financial pressures within NHS Grampian, the MCN is considering a switch to an alternative product. It is acknowledged that more frequent changes to preferred inhaler products may be necessary to help reduce overall treatment costs.

Given the evolving market landscape and the need to publish updated prescribing guidance, the Group agreed to ratify the Respiratory MCN's recommendations at a future meeting. **FD**

ITEM	SUBJECT	ACTION

7. PUBLISHED ADVICE

7.1. SCOTTISH MEDICINES CONSORTIUM ADVICE PUBLISHED JULY 2025

The Group noted the SMC advice published July 2025.

Following publication of the negative SMC recommendations for fezolinetant (Veoza®▼ – SMC 2798), lecanemab (Leqembi®▼ – SMC 2811), and amivantamab (Rybrevant®▼ – SMC 2758), 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 2764 abaloparatide (Eladynos®)▼ (submission expected)
- SMC 2736 osimertinib (Tagrisso®) (submission expected)
- SMC 2767 pembrolizumab (Keytruda®) (submission expected)
- SMC 2733 selpercatinib (Retsevmo®)▼

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

7.2. SCOTTISH MEDICINES CONSORTIUM ADVICE PUBLISHED AUGUST 2025

The Group noted the SMC advice published August 2025.

Following publication of the negative SMC recommendation for dupilumab (Imfinzi® – SMC 2801) and the non-submission statements for letermovir (Prevymis® – SMC 2853) and trastuzumab deruxtecan (Enhertu®▼ – SMC 2854), 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 2762 brentuximab vedotin (Adcetris®) (submission expected)
- SMC 2822 mirikizumab (Omvoh®)▼
- SMC 2821 ripretinib (Qinlock®)▼
- SMC 2819 zanubrutinib (Brukinsa®)▼ (submission expected)

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

7.3. NATIONAL CANCER MEDICINES ADVISORY GROUP ADVICE PUBLISHED JULY 2025

The Group noted the NCMAG advice published July 2025.

The following NCMAG supported medicines have not been processed within a 60-day timescale:

- NCMAG 123 bevacizumab (submission received)
- NCMAG 124 bevacizumab (submission received)

Local advice for this medicine and indications will be included in the August 2025 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'. **FTEAM**

ITEM	SUBJECT	ACTION

8. PROVISIONAL ADVICE

8.1. SCOTTISH MEDICINES CONSORTIUM ADVICE ISSUED AUGUST 2025

The Group noted the SMC provisional advice issued August 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. POLYPHARMACY PRESCRIBING GUIDANCE – DRAFT CONSULTATION

The Chair highlighted that the draft consultation on the updated polypharmacy prescribing guidance closes on the 22 September.

9.2. YELLOW CARD CENTRE SCOTLAND REPORTS 2023/24

Mrs Cameron provided members with an overview of the Yellow Card Centre Scotland Annual Report for 2023/24, including a summary of NHS Grampian-specific data.

Nationally, Yellow Card reporting decreased by 13%, while NHS Grampian experienced a smaller reduction of 5%. Notably, patient submissions accounted for the majority of reports within NHS Grampian, with 234 reports representing 76% of the total.

There were 158 serious reports submitted, comprising 51% of NHS Grampian's total. The region recorded 52 reports per 100,000 population, slightly above the national rate of 50 per 100,000.

Excluding vaccine-related reports, metronidazole was identified as the most frequently reported medicine associated with an adverse reaction in NHS Grampian.

10. DOCUMENTS FOR INFORMATION

Items 10.1 to 10.6 were noted by the Group, including: Medicines and Healthcare products Regulatory Agency (MHRA) Safety Round-ups for June and July 2025; MedWatch Vol.6, Issue 2 (June 2025); and the minutes from the May 2025 meetings of the Grampian Area Drug and Therapeutics Committee, Grampian Primary Care Prescribing Group, and Grampian Medicine Guidelines and Policies Group.

11. AOCB

TIRZEPATIDE LIST PRICE INCREASE

Ms Doney informed the Group that the list price of tirzepatide will increase effective from 01 September 2025. The increase is significant, particularly for higher dose presentations. Ms Doney will circulate the updated pricing information to members following the meeting. **FD**

DATE OF NEXT MEETING

Tuesday 16 September 2025 starting at 14.30 via Microsoft Teams.

Signature on file

CHAIR'S SIGNATURE **Dr Louise Elliot** **DATE 16 SEPTEMBER 2025**