East Region Formulary

East Region Formulary Committee
Minutes

Date: 28 October 2026
Time: 2.00pm – 3:50pm
Location: MS Teams

Present:

Farrah Al-Ghita	Senior Pharmacist - Renal, NHS Fife
Mona Boriceanu	Advanced Nurse Practitioner, NHS Fife
Jane Browning	Associate Director of Pharmacy, NHS Lothian
Malcolm Clubb	Director of Pharmacy (Co-Chair), NHS Borders
Dr Tariq Farrah	Consultant – Renal, NHS Lothian
Carol Holmes	Pharmacist – Primary Care, NHS Lothian
Dr Elliot Longworth	GP, NHS Borders
Lesley Macher	Lead Pharmacist – Medicines Governance and Guidance, NHS Lothian
Dr Iain Macintyre	Consultant – Renal (Co-Chair), NHS Lothian – in the Chair
Joanne Miskelly	Formulary Support Pharmacist, NHS Lothian
Noreen Mohammed	Senior Practice Pharmacist, NHS Fife
Diane Murray	Formulary Pharmacist, NHS Lothian
Fraser Notman	Senior Pharmacist – Medicines Management, NHS Fife
Dr Jo Rose	GP, NHS Lothian
Mandy Wilson	Advanced Cancer Care Pharmacist - Medicines Governance, NHS Lothian

In attendance:
Jessica Dickson, Unit Head - Medicines Policy, Scottish Government
Beth Lambie, Pharmacist – Ophthalmology, NHS Lothian
Jeanna Sandilands, Team Leader - Access to New Medicines Policy Team, Scottish Government
Caitlin Satti, Information Officer, NHS Lothian (minutes)
Jewel (Hui Syuen) Tan, Senior Clinical Pharmacist in BBV and Specialist Clinical Pharmacist in Substance Use, NHS Fife

Apologies:
Dr Grace Ding, Consultant Oncologist, NHS Lothian
Dr Joan Egerton, GP, NHS Fife
Dr David Griffith, Consultant – Microbiologist, NHS Fife
Dr Alice Klauser, Consultant Haematologist and Head of Laboratory Haematology, NHS Lothian
Claire Stoddart, Lead Formulary Pharmacy Technician, NHS Lothian
Dr Monica Szabo, Consultant Oncologist, NHS Lothian
Sarah Tait, Lead Advanced Practitioner, NHS Borders

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1 Welcome and Apologies

The Chair welcomed those present to the East Region Formulary Committee (ERFC).

- ERFC noted that the meeting is being recorded

1.2 Matters arising

1.2.1 ERFC May 2026 Item 3.1.5 Daridorexant: Quviviq (SMC2611) was reviewed at the ERFC May meeting. The ERFC requested further engagement with NHS Fife and NHS Borders ADTCs to clarify whether local Boards would be able to support and implement the proposal, and to better understand the reasons underlying the current lack of support.

It was noted that NHS Fife was not opposed to daridorexant, in principle, but sought further assurance regarding specialist initiation arrangements, ongoing prescribing responsibilities, shared care arrangements, review and monitoring requirements, and discontinuation criteria. The Committee noted that Fife's concerns related predominantly to implementation, governance and sustainability considerations, and that the Board would support further regional work to develop a clear and consistent prescribing pathway across the East Region. Additionally, an update was provided from NHS Borders, noting that no formal ADTC discussion had taken place since the matter was last considered. Members reported limited local demand for daridorexant, with only a small number of non-formulary requests received to date. No significant local demand from specialist services had been identified.

Members discussed the uncertainty surrounding projected patient numbers and whether the estimates provided may underestimate actual demand. It was acknowledged that interest appeared to be arising primarily from general practice where treatment options for chronic insomnia remain limited, particularly in areas where access to specialist sleep services is restricted. However, concerns were expressed that wider availability through primary care could lead to significantly greater prescribing than currently forecast.

The ERFC discussed the proposed specialist initiation status, recognising that this could strengthen governance and help manage workload and demand, but may also increase referrals and place additional pressure on already limited specialist services. Members noted that many patients with chronic insomnia are managed exclusively in primary care and may never meet the threshold for specialist referral. The committee agreed that specialist initiation status was not warranted, and that prescribing in line with SMC advice and the principles of realistic medicine in both primary and secondary care would be appropriate. However, boards may elect to have different local pathways for access to this medicine to be reflected in the formulary pathway update to be agreed with input from stakeholder representatives from the region. Committee members recognised the need for clear prescribing responsibilities, review arrangements, and monitoring criteria regardless of the final pathway adopted.

Upon discussion, the Committee agreed that many of the concerns raised by Boards related to implementation rather than formulary suitability, highlighting the need for further regional discussion on supporting prescribing information, interface arrangements between primary and secondary care, monitoring and review requirements, governance arrangements, and the wider management of sleep disorders. Members acknowledged that implementation of formulary decisions remains the responsibility of individual Boards and agreed that formulary approval should proceed whilst Boards continue work to develop appropriate local implementation arrangements. The committee note that original patient number estimates were based on specialist initiation status and that estimated patient numbers are likely to be higher depending on how boards agree to introduce the medicine locally. The committee recommend that Boards consider local estimates based on local plans for implementation and monitor prescribing trends, addressing any issues as they arise.

<u>The ERFC agreed to classify FAF1 Daridorexant: Quviviq (SMC2611) as Routinely available in line with national guidance. The formulary website will be updated.</u>

ACTION: East Region Formulary Team

1.2.2 ERFC June 2026 Item 3.1.1 FAF1 Dupilumab: Dupixent (SMC2851) was reviewed at the ERFC June meeting. The ERFC requested the submission of the draft prescribing guidance to ensure the queries raised have been addressed, as well as a revised application with corrected NHS Fife Clinical Director support to ensure awareness of budgetary implications.

The representatives of clinical teams are reminded that approval of guidelines remains the responsibility of individual NHS Boards. Where services collaborate to develop regional guidance, each Board is required to progress the document through its own local medicines governance approval process.

Formal support from Clinical Directors in NHS Fife have been obtained and draft prescribing information has been provided. The revised application proposed a specialist initiation formulary flag; however, the Committee considered Specialist Use Only more appropriate.

The ERFC also noted discussion regarding the potential formulary submission of an omalizumab biosimilar for this indication. Whilst this was outside the scope of the current application, members noted that a licensed biosimilar exists, and it was clarified that previous SMC advice relating to the originator product would not prevent submission of a biosimilar application. Given the potential cost-effectiveness benefits associated with biosimilar medicines, applicants were encouraged to consider a future submission if clinically appropriate.

The ERFC agreed to classify FAF1 Dupilumab: Dupixent (SMC2851) as Routinely available in line with national guidance. Included on the ERF for Specialist Use Only. The formulary website will be updated.

ACTION: East Region Formulary Team

1.2.3 ERFC September 2026 Item 3.1.3 FAF1 Isatuximab: Sarclisa (SMC2804) was reviewed at the ERFC September meeting. The ERFC requested the revision of the proposed patient numbers per annum.

The applicants have subsequently reviewed ChemoCare data and confirmed that the original estimate had underestimated likely usage. The forecasted patient numbers were revised from 10 to 20 patients. It was noted that as formulary approval has already been granted, the purpose of the update was to ensure that budget holders were made aware of the revised patient numbers and associated financial implications. Action complete.

1.2.4 ERFC September 2026 Item 3.1.11 FAF3 Blinatumomab (Blincyto) was reviewed at the ERFC September meeting. The ERFC requested clarification from the applicants on whether the indication is intended to be restricted to Philadelphia chromosome-negative patients only as this would narrow the eligible patient population.

The applicants confirmed that this was not their intention and that the proposed use should include both Philadelphia chromosome-negative and Philadelphia chromosome-positive patients, in line with current UK guidance. The ERFC also noted that the applicants had requested the inclusion of a Paediatric License Extension, clarifying that the previous application had included both licensed and off-label use within the intended patient population.

The off-label indication is confirmed as:

Blinatumomab as part of consolidation treatment with chemotherapy for eligible children and young people with newly diagnosed Philadelphia chromosome-negative or Philadelphia-positive patients with CD19-positive B-cell precursor acute lymphoblastic leukaemia.

The ERFC agreed to classify FAF3 Blinatumomab for the as Routinely available in line with national guidance. Included on the ERF for Specialist Use Only. Classified for use under policy for the use of unlicensed medicines. The formulary website will be updated.

The paediatric license extension is confirmed as applying to the existing SMC advice for SMC1145/16 for the treatment of adults with Philadelphia chromosome negative relapsed or refractory B-precursor acute lymphoblastic leukaemia (ALL). In addition to the adult approval, the paediatric license extension is confirmed: as monotherapy for the treatment of paediatric patients aged 1 year or older with high-risk first relapsed Philadelphia chromosome negative CD19 positive B-precursor ALL as part of the consolidation therapy.

The ERFC agreed to classify blinatumomab for the paediatric licence extension as Routinely available in line with local or regional guidance. Included on the ERF for Specialist Use Only. The formulary website will be updated.

2 Governance

2.1 East Region Formulary Committee (ERFC) meeting minutes 02 September 2026

The minutes of the previous meeting were approved as an accurate record with no changes to note.

2.2 East Region Working Group (ERWG) meeting minutes 23 September 2026

The minutes of the ERWG meeting on 23 September 2026 were noted for information.

2.3 East Region Formulary (ERF) sections/amendments for review

2.3.1 ERF Adult – Infections – Dental infections - SDCEP updated guidance

The dental infections pathway has been revised to align with the latest SDCEP recommendations. The amendment removes detailed pathway treatment options from the formulary and directs users to the national Scottish Dental Formulary, ensuring access to the most current and nationally consistent guidance.

The ERFC further noted the retirement of the children's fluoride deficiency pathway as all products previously referenced within the pathway have now been discontinued.

The ERFC approved the amendment. The formulary website will be updated.

ACTION: East Region Formulary Team

2.3.2 ERF Pharmacy First – Parasite Infections - Scabies

The ERFC noted that local users of the Pharmacy First recommendations requested the addition of an information note highlighting the requirement to supply enough treatment to complete a full course.

The ERFC approved the amendment. The formulary website will be updated.

ACTION: East Region Formulary Team

3 New Medicines

3.1 Formulary Application Forms (FAF)

3.1.1 FAF1 Trastuzumab deruxtecan: Enhertu (SMC2545)

The ERFC noted and discussed the previously circulated FAF1 submission. No declarations of interest were received. Named CD support received from all three Boards.

Indication: As monotherapy for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received one or more prior anti-HER2-based regimens.
SMC restriction: in patients who have received one prior anti-HER2-based regimen.

The clinical management guideline and local treatment protocol were included with the FAF.

The ERFC reviewed the submission. It was noted that the application relates to a licence extension for use in unresectable or metastatic HER2-positive breast cancer in patients who have received one prior anti-HER2-based regimen, consistent with SMC advice. The medicine is already available on the formulary for later-line use following previous SMC approval, and is included in the NHS Scotland RDS 'HER2 positive metastatic breast cancer (HER2+ MBC)' guideline. The committee noted that as the treatment can be used in earlier lines of therapy, associated costs are not entirely new as subsequent

cost will be offset. Local estimates of patient numbers are higher than SMC predictions, but are based on local data and, therefore, are considered to be more accurate.

It was noted that trastuzumab deruxtecan is associated with a higher rate of adverse effects than trastuzumab emtansine, including a recognised risk of interstitial lung disease. However, these risks were considered acceptable and manageable within specialist oncology practice and have already been incorporated into existing monitoring arrangements.

The ERFC agreed to classify FAF1 Trastuzumab deruxtecan: Enhertu (SMC2545) as Routinely available in line with national guidance. Included on the ERF for Specialist Use Only. The formulary website will be updated.

ACTION: NHS Lothian Admin Team

3.1.2 FAF1 Amivantamab: Rybrevant (SMC2834)

The ERFC noted and discussed the previously circulated FAF1 submission. No declarations of interest were received. Named CD support received from all three Boards.

Indication: In combination with lazertinib for the first line treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) Exon 19 deletions or Exon 21 L858R substitution mutations.

The clinical management guideline and local treatment protocol were included with the FAF.

The ERFC reviewed the proposed inclusion of Amivantamab, providing an additional first-line treatment choice alongside the existing option of Osimertinib in combination with chemotherapy. Treatment selection will be guided by individual patient factors, including toxicity profile, co-morbidities, baseline fitness, ability to attend frequent day-case appointments, and preference for a chemotherapy-sparing approach. Osimertinib plus chemotherapy will, therefore, remain a first-line treatment option for this patient group alongside amivantamab plus lazertinib.

The ERFC agreed to classify FAF1 Amivantamab: Rybrevant (SMC2834) as Routinely available in line with national guidance. Included on the ERF for Specialist Use Only. The formulary website will be updated.

ACTION: East Region Formulary Team

3.1.3 FAF1 Durvalumab: Imfinzi (SMC2818)

The ERFC noted and discussed the previously circulated FAF1 submission. One personal specific declaration of interest noted, another consultant oncologist without any declarations of interest provided support. Named CD support received from all three Boards.

Indication: As monotherapy for the treatment of adults with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy.

The clinical management guideline and local treatment protocol were included with the FAF.

The ERFC reviewed the submission. The proposed patient selection criteria will be as per the ADRIATIC trial and SMC recommendations, for patients who tolerate concurrent chemo-radiotherapy for small cell lung cancer, without significant toxicity post treatment and whose cancer has not progressed.

Members noted a potential for variance between the estimated treatment duration given that data collection is ongoing. The application estimates costs based on a median treatment duration of

approximately 40 weeks (10 treatment cycles), consistent with the median duration reported in the ADRIATIC study.

The ERFC, therefore, requests confirmation that the estimated duration from the early data cut off is projected to stay the same once data collection is complete. The applicants are requested to respond with information on the recommended actions by 17 November 2026 (or a future paper deadline, see East Region Formulary for dates).

ACTION: East Region Formulary Team

Additionally, it was noted that the application and accompanying treatment protocol included a statement that durvalumab could be considered following sequential chemotherapy and radiotherapy on a case-by-case basis after discussion with a consultant lung oncologist. However, members observed that the SMC-approved indication refers to use in patients whose disease has not progressed following platinum-based chemoradiation therapy, and the supporting evidence from the ADRIATIC study was in patients who had completed chemoradiotherapy. It is the opinion of the committee that the criteria proposed in the application is not aligned to SMC advice though the application suggests the local clinicians have interpreted this differently.

The ERFC requests clarification of the interpretation of alignment of patient selection criteria to SMC advice. The ERFC recommend that patients treated with sequential chemoradiotherapy will be considered case by case through agreed non-formulary process. The applicants are requested to respond with information on the recommended actions by 17 November 2026 (or a future paper deadline, see East Region Formulary for dates).

ACTION: East Region Formulary Team

The ERFC agreed to classify FAF1 Durvalumab: Imfinzi (SMC2818) as Routinely available in line with national guidance. Included on the ERF for Specialist Use Only. The formulary website will be updated.

ACTION: East Region Formulary Team

3.1.4 FAF1 Durvalumab: Imfinzi (SMC2880)

The ERFC noted and discussed the previously circulated FAF1 submission. No declarations of interest were received. Named CD support received from all three Boards.

Indication: In combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by durvalumab as monotherapy adjuvant treatment after radical cystectomy, for the treatment of adults with resectable muscle invasive bladder cancer (MIBC).

The clinical management guideline and local treatment protocol were included with the FAF.

The ERFC reviewed the submission, noting that the estimated patient population was higher than that reported by the SMC. However, as the estimates were based on ChemoCare data, they were considered more representative of the SCAN population.

Minimal wider service impact is expected, with additional appointment and prescribing/verification episodes only occurring for the adjuvant monotherapy durvalumab.

The ERFC agreed to classify FAF1 Durvalumab: Imfinzi (SMC2880) as Routinely available in line with national guidance. Included on the ERF for Specialist Use Only. The formulary website will be updated.

ACTION: East Region Formulary Team

3.1.5 FAF1 Enfortumab Vedotin: Padcev (SMC2842)

The ERFC noted and discussed the previously circulated FAF1 submission. One personal non-specific declaration of interest was received. Named CD support received from all three Boards.

Indication: In combination with pembrolizumab, for the first-line treatment of adult patients with unresectable or metastatic urothelial cancer who are eligible for platinum-containing chemotherapy.
SMC restriction: treatment with pembrolizumab is subject to a two-year clinical stopping rule.

The clinical management guideline and local treatment protocol were included with the FAF.

The ERFC reviewed the submission, noting that enfortumab vedotin in combination with pembrolizumab replaces current first line treatment of platinum-based chemotherapy (cisplatin or carboplatin) with gemcitabine for up to six cycles. Currently following platinum-based chemotherapy, if disease is stable or a complete or partial response is achieved, patients can receive first line maintenance treatment with avelumab until progression or unacceptable toxicity. Clinicians expect the majority of patients will now be allocated enfortumab vedotin first line, and these patients would not receive avelumab maintenance. The Clinical Management Guideline will be updated to reflect.

Evidence in support of enfortumab vedotin for the proposed indication is noted in respective European Society for Medical Oncology and European Association of Urology guidelines.

The ERFC agreed to classify FAF1 Enfortumab Vedotin: Padcev (SMC2842) as Routinely available in line with national guidance. Included on the ERF for Specialist Use Only. The formulary website will be updated.

ACTION: East Region Formulary Team

3.1.6 FAF1 Vorasidenib: Voranigo (SMC2844)

The ERFC noted and discussed the previously circulated FAF1 submission. One personal non-specific declaration of interest was received. Named CD support received from all three Boards.

Indication: For the treatment of Grade 2 astrocytoma or oligodendroglioma with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation or isocitrate dehydrogenase-2 (IDH2) mutation in adults and paediatric patients 12 years and older, who are not in need of immediate chemotherapy or radiotherapy following surgical intervention.

The clinical management guideline and local treatment protocol were included with the FAF.

The ERFC noted the proposed inclusion of Vorasidenib as the first treatment licensed for the treatment of Grade 2 IDH-mutant astrocytoma or oligodendroglioma. It will be used in place of active surveillance, with clinical experts consulted by the SMC considering that vorasidenib is a therapeutic advance for this relatively young group of patients.

The introduction of vorasidenib is expected to have an impact on the service. Current standard of care is active surveillance where patients are reviewed approximately once or twice a year. Vorasidenib requires complete blood count monitoring prior to starting treatment, every 2 weeks during the first 2 months of treatments, and then monthly for the first 2 years of treatment (and as clinically indicated thereafter). As this is the first oral SACT requiring out-patient clinic delivery for the CNS tumour group team, the clinical team have advised that new pathways are being implemented and NMP resource is being scoped for long-term management of these patients. Committee members acknowledged that the current ECC CNS consultant team currently have capacity to manage patients whilst NMP resource is explored, and training is undertaken.

Overall, the safety profile of vorasidenib is considered acceptable. The primary issue identified was related to hepatotoxicity, however these events were considered manageable with appropriate dose modifications.

The ERFC agreed to classify FAF1 Vorasidenib: Voranigo (SMC2844) as Routinely available in line with national guidance. Included on the ERF for Specialist Use Only. The formulary website will be updated.

ACTION: East Region Formulary Team

3.1.7 FAF1 Tebentafusp: Kimmtrak (SMC2910)

The ERFC noted and discussed the previously circulated FAF1 submission. No declarations of interest were received. Named CD support received from all three Boards.

Indication: As monotherapy for the treatment of human leukocyte antigen (HLA)-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma.

The clinical management guideline and local treatment protocol were included with the FAF.

The committee reviewed the submission, noting that tebentafusp is the first SMC-approved treatment for metastatic uveal melanoma. Previously, patients would typically have received pembrolizumab or nivolumab in combination with ipilimumab.

Tebentafusp is the first SMC-approved bispecific T-cell engager (BiTE) for oncology services. Therefore, SCAN patients will initially receive treatment as inpatients at the Edinburgh Cancer Centre for the first three step-up doses, after which administration may transfer to the day-case unit. In the initial implementation phase, all treatment will remain centralised at the Edinburgh Cancer Centre whilst experience is gained with this new class of drug.

The ERFC agreed to classify FAF1 Tebentafusp: Kimmtrak (SMC2910) as Routinely available in line with national guidance. Included on the ERF for Specialist Use Only. The formulary website will be updated.

ACTION: East Region Formulary Team

3.1.8 FAF1 Upadacitinib: Rinvoq (SMC2879)

The ERFC noted and discussed the previously circulated FAF1 submission. One Personal specific, one personal non-specific, one non-personal specific and one non-personal non-specific declarations were received. Another consultant without declarations of interest supported the application. Named CD support received from all three Boards.

Indication: For the treatment of giant cell arteritis in adult patients.
SMC restriction: for use in patients where tocilizumab is unsuitable, not tolerated or has failed.

The ERFC reviewed the proposed inclusion of upadacitinib as a third-line treatment option, acknowledging that current practice involves corticosteroids, with tocilizumab as the preferred first-line steroid-sparing treatment. Upadacitinib is proposed for use where tocilizumab is unsuitable, not tolerated or ineffective, in line with SMC advice and local treatment pathways. Prescribing will be initiated by specialist rheumatology teams and supplied through established Homecare arrangements.

The committee noted that local guidance will require updating to incorporate upadacitinib, and that the existing one-year stopping rule for tocilizumab should be removed to align with current clinical guidance, allowing treatment duration to be determined by disease activity and clinical need. It was

also noted that the NHS Fife pathway should be updated to include relevant contraindications and cautions for upadacitinib.

The ERFC agreed to classify FAF1 Upadacitinib: Rinvoq (SMC2879) as Routinely available in line with national guidance. Included on the ERF for Specialist Use Only. The formulary website will be updated.

ACTION: East Region Formulary Team

3.1.9 FAF2 Pazopanib (NCMAG128)

The ERFC noted and discussed the previously circulated FAF2 submission. No declarations of interest were received. Named CD support received from all three Boards.

Indication: For the treatment of adult patients with selective subtypes of advanced soft tissue sarcoma who have received prior chemotherapy for metastatic disease or who have progressed within 12 months of (neo) adjuvant therapy

The ERFC reviewed the submission, noting the proposal to include pazopanib for patients with selected non-adipocytic soft tissue sarcoma subtypes, an ECOG performance status of 0–2, and disease progression following, or unsuitability for, first-line anthracycline-based chemotherapy. Pazopanib will provide an additional treatment option and may be the preferred medicine choice following first-line palliative chemotherapy for selected soft tissue sarcoma subtypes given its favourable toxicity profile, convenience, and ease of administration.

Pazopanib is recommended as a treatment option for the proposed indication in the respective European Society of Medical Oncology, British Sarcoma Group, and National Comprehensive Cancer Network guidelines.

The ERFC agreed to classify FAF2 Pazopanib: Votrient (NCMAG128) as Routinely available in line with national guidance. Included on the ERF for Specialist Use Only. The formulary website will be updated.

ACTION: East Region Formulary Team

3.1.10 FAF2 Ethinylestradiol/dropsirenone: Yacella/Dretine

The ERFC noted and discussed the previously circulated FAF2 submission. One personal non-specific declaration of interest was received. Named CD support received from all three Boards.

Indication: Fourth generation combined hormonal contraception. Restricted to use after trial of two alternative COC (with different progestogen component) where symptoms of Pre-Menstrual Syndrome (PMS), fluid retention or acne persist.

The committee considered the proposed inclusion of ethinylestradiol/drospirenone (Yacella/Dretine) as a fourth-generation combined oral contraceptive (COC), and noted that the evidence provided did not demonstrate clinically meaningful advantages over existing formulary options for mood changes, fluid retention, weight gain or other tolerability outcomes. Members noted that the originator product (Yasmin) was not accepted by SMC due to the absence of a sufficiently robust economic case, and that, although branded generic preparations are less expensive than Yasmin, they remain more costly than several existing formulary options.

The original wording proposed was considered to include clinical considerations for which the submission did not provide sufficient evidence to justify preferential use of the higher-cost option. It was noted that alternative, more cost-effective options are available for the management of acne. The ERFC, therefore, agreed on revised wording that more closely reflected the evidence and rationale

presented, restricting use of ethinylestradiol/drospirenone to patients who have trialled at least two alternative combined oral contraceptives containing different progestogens and continue to experience symptoms of PMS, fluid retention or acne.

The ERFC discussed that drospirenone-containing COCs are associated with a higher risk of venous thromboembolism than levonorgestrel-containing preparations, although the absolute risk remains low in healthy women. The committee agreed that lower-risk formulary options should remain first-line and that use of drospirenone-containing COCs should follow an informed risk-benefit discussion.

The committee also discussed wider issues relating to the current contraception formulary, including the large number of available combined oral contraceptive products and the need for a broader review of the ERF contraception section. It was agreed that any wider pathway amendments should be considered through the chapter expert working group.

The ERFC agreed to classify FAF2 Ethinylestradiol/dropsirenone: Yacella/Dretine as Routinely available in line with local or regional guidance. The formulary website will be updated.

ACTION: East Region Formulary Team

3.1.11 FAF3 Tocilizumab (Still's)

The ERFC noted and discussed the previously circulated FAF3 submission. No declarations of interest were received. Named CD support received from all three Boards.

Indication: Treatment of adult-onset Still's disease (AOSD) in adults who are refractory to, or intolerant of, corticosteroids and conventional synthetic DMARDs (e.g. methotrexate).

The ERFC reviewed the submission. It was noted that the inclusion of tocilizumab for the proposed indication is as a third-line treatment option, initiated and supervised by secondary care rheumatology services, for adults with confirmed adult-onset Still's disease (AOSD) who have failed to respond to, are intolerant of, or have contraindications to corticosteroids and at least two DMARDs (e.g. methotrexate, ciclosporin, leflunomide, azathioprine or mycophenolate). NSAIDs and corticosteroids would be used as first-line treatment, followed by conventional synthetic DMARDs as second-line therapy. Tocilizumab or anakinra would be considered third-line options, with the choice of biologic determined by patient-specific criteria.

Members noted that although tocilizumab is not licensed for AOSD, it is licensed for several rheumatological indications, including systemic juvenile idiopathic arthritis, which is widely considered to be closely related to AOSD. Evidence from clinical studies, registry data, and the NHS England commissioning policy supports its effectiveness in reducing disease activity and corticosteroid exposure in patients with refractory disease.

The committee discussed the positioning of tocilizumab relative to the existing formulary option, anakinra. It was noted that clinical practice differentiates between disease phenotypes, with tocilizumab generally favoured in patients with predominant arthritic manifestations, whilst anakinra is preferred where systemic features predominate. The proposed addition was, therefore, viewed as providing an additional treatment option rather than replacing existing therapy.

Given the complexity of treatment positioning and variation in published evidence and clinical practice, the ERFC recommended the development of regional prescribing guidance for adult-onset Still's disease. The guidance should define the place of tocilizumab, clarify when tocilizumab should be selected in preference to anakinra, and provide recommendations on patient selection, dosing, route of administration, treatment escalation and de-escalation, monitoring requirements, response assessment and stopping criteria. The committee recommended that the guidance should draw on the existing NHS England commissioning policy to ensure consistency with established national practice

whilst supporting safe and effective use within the East Region. Lead applicants should note that guideline approval is a matter for individual Boards. Where specialist services in all three Boards collaborate to produce a regional guideline, each Board must complete its own local approval process.

The safety profile was considered well established and broadly comparable to that of anakinra, with monitoring requirements already familiar to specialist teams. Key risks include infection, liver function abnormalities, cytopenias and lipid abnormalities, all of which are managed through existing biologic monitoring pathways.

The ERFC agreed to classify FAF3 Tocilizumab as Routinely available in line with local or regional guidance. Included on the ERF for Specialist Use Only. Classified for use under policy for the use of unlicensed medicines. The formulary website will be updated.

ACTION: East Region Formulary Team

3.1.12 FAF3 Melatonin

The ERFC noted and discussed the previously circulated FAF3 submission. No declarations of interest were received. Named CD support received from all three Boards.

Indication: REM sleep behaviour disorder (RBD) in Parkinson's disease and related alpha synucleinopathies (Multiple System Atrophy: MSA and Dementia with Lewy Bodies: DLB).

The ERFC noted the proposed inclusion of Melatonin for use in patients with confirmed idiopathic Parkinson's disease under regular secondary-care management and follow-up who have REM Sleep Behaviour Disorder that is significantly affecting sleep quality and/or quality of life for the patient or bed partner. Sleep hygiene measures should have been tried without benefit, and patients should have either not benefited from, or be unsuitable for, night sedation due to factors such as falls risk or dementia.

The supporting evidence was primarily based on NICE guidance which recommends considering melatonin or clonazepam for RBD. Melatonin was viewed favourably due to its more positive safety profile compared with clonazepam, particularly in older patients with Parkinson's disease where clonazepam may increase the risk of drowsiness, confusion, hypotension, and falls. Members noted that melatonin is generally well tolerated, with mild drowsiness and headache being the most commonly reported adverse effects. Unlike clonazepam, it is not associated with significant cognitive impairment, dependency or withdrawal symptoms, making it suitable for longer-term use. Treatment initiation would be restricted to the specialist neurology, Medicine of the Elderly, and Parkinson's disease teams, and patients would be required to meet defined protocol criteria before treatment is commenced.

It was noted that a separate formulary application covering melatonin use across a wider range of sleep disorders is expected. It was, therefore, agreed that melatonin for the proposed indication should be included in the Formulary Decisions section only, with its formulary positioning to be considered further as part of the wider sleep disorders pathway review.

The ERFC agreed to classify FAF3 Melatonin as Routinely available in line with local or regional guidance. Included on the ERF for Specialist Initiation. Classified for use under policy for the use of unlicensed medicines. The formulary website will be updated.

ACTION: East Region Formulary Team

3.2 Formulary Amendment Form

3.2.1 Thiamine

The ERFC noted and discussed the previously circulated Formulary Amendment form. No declarations of interest were received. Clinical team support received from all three Boards.

Indication: Alcohol withdrawal.

Application for amendment to include a new intravenous thiamine 250mg/2mL ampoule formulation for use in alcohol withdrawal, thiamine replacement, and the management or prevention of Wernicke's encephalopathy. The new concentration is already available on contract and is substantially more cost-effective than the existing 250mg/5mL product.

The proposed amendment is to make the 250mg/2mL formulation the preferred formulary option, whilst retaining the existing formulation to mitigate potential supply shortages.

The formulary website will be updated.

ACTION: East Region Formulary Team

3.2.2 Omalizumab (Omlyclo)

The ERFC noted and discussed the previously circulated Formulary Amendment form. No declarations of interest were received. Clinical team support received from all three Boards.

Indication: Chronic Spontaneous Urticaria, Allergic Asthma.

Application for amendment to include new biosimilar formulations of Omalizumab (Omlyclo), including 300mg pre-filled syringes and pre-filled pens, for use in allergic asthma and chronic spontaneous urticaria. The rationale for the amendment is to reduce treatment burden by allowing patients requiring a 300mg dose to administer a single injection rather than two 150mg injections. The addition of pen devices also provides greater administration choice for patients.

The formulary website will be updated.

ACTION: East Region Formulary Team

3.3 Ultra Orphan Medicines Initial Assessment

3.3.1 None.

3.4 SMC not recommended advice

The ERFC noted the SMC not recommended advice for information.

3.4.1 Depemokimab: Exdensur (SMC2970)
3.4.2 Hydrocortisone: Efmody (SMC2971)
3.4.3 Lisocabtagene maraleucel: Breyanzi (SMC2972)
3.4.4 Sotatercept: Winrevair (SMC2973)
3.4.5 Toripalimab: Loqtorzi (SMC2974)

The formulary website will be updated.

ACTION: East Region Formulary Team

3.5 Abbreviated submissions

3.5.1 Seladelpar: Livdelzi (SMC2946)

The ERFC noted the SMC abbreviated submission for Seladelpar: Livdelzi (SMC2946).

Indication: For the treatment of primary biliary cholangitis (PBC), including pruritus, in adults in combination with ursodeoxycholic acid (UDCA) who have an inadequate response to UDCA alone, or as monotherapy in those unable to tolerate UDCA.

The ERFC agreed to classify Seladelpar: Livdelzi (SMC2946) as 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. The formulary website will be updated.

ACTION: East Region Formulary Team

3.5.2 Deuruxolitinib: Leqselvi (SMC2968)

The ERFC noted the SMC abbreviated submission for Deuruxolitinib: Leqselvi (SMC2968).

Indication: Treatment of adult patients with severe alopecia areata.

The ERFC noted the proposed inclusion of deuruxolitinib as a second-line JAK inhibitor option in the alopecia areata pathway. It is intended to be used where first-line treatment with ritlecitinib (Litfulo) has been ineffective, not tolerated, or becomes contraindicated.

The committee noted that deuruxolitinib is licensed only for adults aged 18 years and over, whereas ritlecitinib is licensed from 12 years of age. Consequently, the anticipated patient population is expected to be small. A local dermatology treatment pathway has been developed in collaboration with the Scotland Hair Group while updated national guidance from the British Association of Dermatologists is awaited. The pathway specifies eligibility criteria, response assessment at 36 weeks, monitoring requirements and treatment sequencing. Deuruxolitinib is positioned after ritlecitinib failure or intolerance and requires additional CYP2C9 genotyping prior to initiation.

The ERFC agreed to classify Deuruxolitinib: Leqselvi (SMC2968) as Routinely available in line with national guidance. Included on the ERF for Specialist Use Only. The formulary website will be updated.

ACTION: East Region Formulary Team

3.6 Paediatric licence extensions

3.6.1 None noted.

3.7 Non-submissions within 90 days of SMC publishing

The ERFC noted the non-submissions within 90 days of SMC publishing.

3.7.1 Nusinersen: Spinraza (SMC2877)
3.7.2 Epcoritamab: Tepkinly (SMC2881)
3.7.3 Pembrolizumab: Keytruda (SMC2907)
3.7.4 Capivasertib: Truqap (SMC2930)
3.7.5 Elacestrant: Korserdu (SMC2933)
3.7.6 Lorlatinib: Lorviqua (SMC2867)
3.7.7 Atidarsagene autotemcel: Libmeldy (SMC2886)

The ERFC agreed to classify item 3.7.1, 3.7.2, 3.7.3, 3.7.4, 3.7.5, 3.7.6, and 3.7.7 as 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. The formulary website will be updated.

ACTION: East Region Formulary Team

3.8 National Cancer Medicines Advisory Group

3.8.1 None.

3.9 Scottish Medicines Consortium

3.9.1 None.

4 Board specific information

4.1 NHS Borders

None raised.

4.2 NHS Fife

None raised.

4.3 NHS Lothian

None raised.

5 Any other competent business

None raised.

6 Date of next meeting

The next ERFC meeting is scheduled for Wednesday 9th December 2026 at 1400 - 1630 hours via MS Teams. NHS Lothian will be hosting the meeting.

FAF3s should be submitted by 05 January 2027 (for discussion at the ERWG meeting on 20 January 2027).

FAF1s and FAF2s should be submitted by 17 November 2026.

All FAFs need to include information on proposed use and confirmation of Clinical Director (or equivalent medical manager) support from all three Boards (including names), to be added to the agenda. In the case where the service is only provided by one of the Boards, this should be clearly stated in the application. Confirmation of Clinical Director (or equivalent medical manager) support from all three boards is required where cross-Board charging applies.

Apologies for the meeting to be sent to eos.prescribing@nhs.scot.