NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 16 June 2026 at 14:30 via Microsoft Teams

APPROVED

ITEM **SUBJECT** **ACTION**

WELCOME

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

1. ATTENDANCE, APOLOGIES AND DEPUTIES

1.1. CHAIR

Dr Louise Elliot, Chair.

1.2. MEMBERS PRESENT

Present	Apologies	Deputies
	Mr Y Al-Obaidi	Mrs E Bruce
	Mr G Burt	
Ms L Cameron		
Dr V Chieng		
Ms F Doney		
Dr L Elliot		
Mrs M Galvin		
Mrs E Milne		
Mrs S O'Beirne		
Mr M Paterson		

1.3. IN ATTENDANCE

Ms D Bruce, Specialist Pharmacy Technician, Formulary Team.
Mrs C Standen, Formulary and Medicines Management Pharmacist.

1.4. NOTES

Members who sent apologies are recorded.

2. MINUTE AND DECISIONS

2.1. DRAFT MINUTES OF THE MEETING HELD 19 MAY 2026

Members approved the minutes of the previous meeting, subject to minor typographical amendments.

The approved minutes will be made publicly available within 21 days of approval. **FD**

2.2. FORMULARY GROUP DECISIONS MAY 2026 - PUBLISHED 02/06/2026

Members formally ratified the May 2026 decisions document as published.

3. MATTERS ARISING

3.1. ACTION LOG

The Group noted the item.

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3.2. AMIKACIN LIPOSOMAL 590MG NEBULISER DISPERSION (ARIKAYCE®) - FEEDBACK

At the May meeting, the Group highlighted uncertainty regarding the responsibility and pathways for monitoring auditory and vestibular toxicity associated with amikacin (Arikayce®).

The Group was broadly supportive of the service's proposed communication approach to support inclusion in the Emergency Care Summary (ECS) as a hospital-prescribed medicine, and including the use of standard wording to inform primary care when Arikayce® is prescribed and provision of a link to the Summary of Product Characteristics (SmPC). However, the Group requested that the accompanying information is further developed, with clearer highlighting of potential adverse effects, for example auditory and vestibular adverse effects, alongside the SmPC link within prescriber communications. **FD**

The Group noted the importance of ensuring relevant information is clearly visible within primary care systems, including within the patient record. Members suggested implementation of an alert or flag to support identification of potential adverse effects. Ms Doney and the primary care pharmacy members to liaise with relevant pharmacy leads to progress enhancements to prescriber communication and patient record alerts. **FD**

3.3. REVIEW OF PREVIOUS ACTION LOG

Ms Doney presented updates and closure plans for several longstanding items on the previous action log, including audits, reviews, and feedback on specific medicines. The Group agreed to close the old action log and revisit certain items as needed in the future. **FTEAM**

4. DISCUSSION/PRESENTATION

None.

5. NEW PRODUCT REQUESTS

5.1. FG1SMC 2623 - DIFELIKEFALIN (MODERATE TO SEVERE PRURITUS ASSOCIATED WITH CHRONIC KIDNEY DISEASE)

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

The Group considered the request for difelikefalin as a treatment option for moderate-to-severe pruritus associated with chronic kidney disease in adults on haemodialysis who have an inadequate response to best supportive care for reducing itch.

The Group noted that:

- difelikefalin:
  - acts on kappa opioid receptors on peripheral sensory neurons and immune cells to produce antipruritic and anti-inflammatory effects
  - is administered three times per week by intravenous bolus injection into the venous line of the dialysis circuit at the end of the haemodialysis treatment during rinse-back or after rinse-back
  - [for this indication] the recommended dose is 0.5micrograms/kg dry body weight (i.e., the target post-dialysis weight). An effect of difelikefalin in reducing pruritus is expected after 2-3 weeks of treatment.
  - is the first medicine licensed in the UK for the treatment of haemodialysis-associated pruritus in patients with chronic kidney disease. The service currently use off-label mirtazapine, gabapentin or pregabalin for this indication.
  - meets SMC orphan equivalent criteria for this indication
- evidence of efficacy comes from KALM-1 and KALM-2, placebo-controlled phase III

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studies. Patients were randomised equally to difelikefalin (KALM-1: n=189, KALM-2: n=237) or placebo (KALM-1: n=189, KALM-2: n=236).

- the primary outcome was ≥3-point improvement in Worst Itching Intensity Numerical Rating Scale (WI-NRS) at week 12:
  - KALM-1: 51% for difelikefalin and 28% for placebo
  - KALM-2: 54% for difelikefalin and 42% for placebo
- there is a lack of long-term safety data beyond 15 months and pharmacovigilance activities are ongoing to monitor longer-term adverse events such as MACE (Major Adverse Cardiovascular Events)
- the service plans to treat patients with difelikefalin for 12 weeks and if WI-NRS score does not improve by at least 3 points, treatment will be discontinued
- the service has stated that there is no direct replacement for difelikefalin as they would trial other drugs (e.g. mirtazapine, gabapentin, pregabalin [all off-label]) first then difelikefalin
- the sequence of treatments would be topical emollient, addition of topical menthol, addition of mirtazapine/gabapentinoid, addition of difelikefalin. To reduce treatment burden, any ineffective treatment (topical, oral or intravenous) would be discontinued, with continuation of therapies deemed to provide clinical benefit.
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of difelikefalin
- the PAS is only available to secondary care

The Group accepted the restricted local need for a difelikefalin for the treatment of moderate-to-severe pruritus associated with chronic kidney disease in adults on haemodialysis who have an inadequate response to best supportive care for reducing itch.

FG1SMC 2623 - Difelikefalin 50micrograms/mL solution for injection (Kapruvia®)▼ is routinely available in line with national guidance (SMC 2623).
Indication under review: treatment of moderate-to-severe pruritus associated with chronic kidney disease in adults on haemodialysis who have an inadequate response to best supportive care for reducing itch.
Difelikefalin, compared with placebo, improved itch for a greater proportion of patients with moderate-to-severe itch who were undergoing haemodialysis for end-stage renal 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.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Kapruvia® should be restricted for in-centre haemodialysis use only. Kapruvia® is intended for use by healthcare professionals experienced in the diagnosis and treatment of conditions for which difelikefalin is indicated. Causes of pruritus other than chronic kidney disease should be excluded before initiating treatment with difelikefalin. FTEAM

5.2. FG1SMC 2844 - VORASIDENIB (GRADE 2 ASTROCYTOMA OR OLIGODENDROGLIOMA)

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

The Group considered the request for vorasidenib 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.

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The Group noted:

- vorasidenib:
  - inhibits mutant IDH1 and IDH2 enzymes, which in astrocytoma or oligodendroglioma are responsible for the overproduction of 2-hydroxyglutarate which impairs cell differentiation and contributes to oncogenesis
  - is the first treatment licensed for the treatment of Grade 2 IDH-mutant astrocytoma or oligodendroglioma
  - [for this indication] meets SMC orphan criteria, and was accepted for use in NHS Scotland following a full submission assessed under the orphan medicine process, the output from the PACE process, and application of SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios
- the recommended adult dose of vorasidenib is 40mg orally once daily. For adolescents aged 12 years and over, dosing is weight-based, with 40mg once daily recommended for patients weighing at least 40kg and 20mg once daily for those weighing less than 40kg.
- the current standard of care for this patient population is active surveillance
- testing for IDH1 and IDH2 mutations are already carried out routinely
- evidence for the safety and efficacy of vorasidenib comes from INDIGO trial. Patients were randomised to vorasidenib 40mg orally once daily (n=168) or placebo (n=163)
  - the primary outcome was radiographic progression free survival (PFS)
  - the median PFS was 27.7 months for vorasidenib versus 11.1 months for placebo
- patient numbers are expected to be very small
- the median duration of treatment in the INDIGO trial for the vorasidenib group was 12.6 months but the median progression free survival was 27.7 months
- this will be a new cost as current standard of care for this patient group is active surveillance.
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of vorasidenib, the PAS is only available to secondary care

The Group accepted the restricted local need for vorasidenib for the treatment of Grade 2 astrocytoma or oligodendroglioma with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation or isocitrate dehydrogenase-2 (IDH2) mutation, as outlined in SMC 2844.

FG1SMC 2844 - Vorasidenib 10mg, 40mg film-coated tablets (Voranigo®)▼ is routinely available in line with national guidance (SMC 2844).
Indication under review: 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.
In a randomised, double-blind phase III study, vorasidenib significantly improved radiographic progression-free survival compared with placebo in patients with IDH-mutant Grade 2 astrocytoma or oligodendroglioma who were post-surgery and not in need of immediate chemotherapy or radiotherapy.
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 and supervised by a physician experienced in the use of anti-cancer medicinal products. Select patients for the treatment of astrocytoma or oligodendroglioma with vorasidenib based on the presence of IDH1 or IDH2 mutations in tumour specimens using an appropriate diagnostic test prior to initiation of treatment with vorasidenib. FTEAM

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5.3. FG1SMC 2893 - ACALABRUTINIB (ADULTS WITH PREVIOUSLY UNTREATED CHRONIC LYMPHOCYTIC LEUKAEMIA (CLL))

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

The Group considered the request for acalabrutinib used in combination with venetoclax for the treatment of adults with previously untreated chronic lymphocytic leukaemia (CLL).

The Group noted:

- acalabrutinib is a selective inhibitor of Bruton tyrosine kinase (BTK)
- the recommended dose of acalabrutinib in monotherapy or in combination with other medicinal products is 100mg orally twice daily (equivalent to a total daily dose of 200mg). Acalabrutinib dose interval is approximately 12 hours.
- treatment with acalabrutinib in combination with venetoclax, should continue until disease progression, unacceptable toxicity or completion of 14 cycles of treatment (each cycle is 28 days)
- ibrutinib, another BTK inhibitor, is included on formulary for this indication
- evidence comes from the AMPLIFY trial. Patients were randomised to receive acalabrutinib plus venetoclax (n=291) or investigators choice of chemotherapy (n=290).
- the primary outcome was PFS. Estimated 36-month PFS was 76% with acalabrutinib plus venetoclax and 66% with chemo immunotherapy.
- an indirect treatment comparison indicated that there was no clear evidence of a difference in PFS and overall survival (OS) between acalabrutinib plus venetoclax and ibrutinib plus venetoclax.
- patient numbers are expected to be very small
- the service has stated that acalabrutinib plus venetoclax will be used to complement current first-line options, ibrutinib plus venetoclax or obinutuzumab plus venetoclax, specifically in patients who have cardiovascular disease/risk and where a fixed duration therapy is desirable
- the service states that, compared with ibrutinib, acalabrutinib is associated with fewer cardiovascular side effects, notably a lower rate of atrial fibrillation and sudden cardiac death. In addition, acalabrutinib plus venetoclax compared with obinutuzumab and venetoclax, there are fewer infusion reactions and no need for hospitalisation for treatment.
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of acalabrutinib

The Group accepted the restricted local need for acalabrutinib, used in combination with venetoclax, as an alternative first-line treatment option for adults with previously untreated CLL.

FG1SMC 2893 - Acalabrutinib 100mg film-coated tablets (Calquence®) is routinely available in line with national guidance (SMC 2893).
Indication under review: in combination with venetoclax for the treatment of adults with previously untreated chronic lymphocytic leukaemia (CLL).
Acalabrutinib in combination with venetoclax offers an additional treatment choice in the therapeutic class of Bruton tyrosine kinase (BTK) inhibitors to be used in combination with B-cell lymphoma-2 inhibitors.
Another Bruton tyrosine kinase (BTK) inhibitor was accepted for use under the orphan equivalent medicine process.
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

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	8b - recommended for hospital use only. Treatment with this medicinal product should be initiated and supervised by a physician experienced in the use of anticancer medicinal products.	FTEAM

5.4. FG1SMC 2829 - PEMBROLIZUMAB (CERVICAL CANCER)

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

The Group considered the request for pembrolizumab in combination with chemoradiotherapy (external beam radiation therapy followed by brachytherapy), for the treatment of FIGO 2014 Stage III - IVA locally advanced cervical cancer in adults who have not received prior definitive therapy.

The Group noted:

- pembrolizumab:
  - is a humanised monoclonal antibody which blocks the interaction between the programmed death-1 (PD-1) receptor and its ligands PD-L1 and PD-L2
  - is already included on NHS Grampian formulary for multiple indications
- for locally advanced cervical cancer, patients should be treated with pembrolizumab concurrent with chemoradiotherapy, followed by pembrolizumab as monotherapy
- pembrolizumab can be administered intravenously as 200mg every three weeks or 400mg every six weeks or subcutaneously as either 395mg every 3 weeks or 790mg every 6 weeks until disease progression, unacceptable toxicity or up to 24 months
- the service plan to treat with subcutaneous pembrolizumab now that it is available
- evidence comes from KEYNOTE-A18:
  - patients were treated with intravenous pembrolizumab 200mg every 3 weeks for 5 cycles or placebo, in combination with chemoradiotherapy, followed by pembrolizumab 400mg every 6 weeks for 15 cycles or placebo.
  - the co-primary outcomes were PFS and OS, at interim analysis 1 and 2 the median PFS and OS were not reached
  - at interim analysis 2 the 12-month PFS rate was 82% for the pembrolizumab plus chemoradiotherapy group versus 70% for placebo plus chemoradiotherapy. The 24-month OS rate was 87% for the pembrolizumab plus chemoradiotherapy and 78% for placebo plus chemoradiotherapy.
- initially patient numbers will be low but cumulative from year 2
- at interim analysis 2, the median treatment duration was 19 months in the pembrolizumab plus chemoradiotherapy group but median PFS was not reached at this point
- the service has stated that pembrolizumab plus chemoradiotherapy will be used instead of radical chemoradiotherapy alone or neoadjuvant chemotherapy with weekly Carboplatin/Paclitaxel prior to definitive chemoradiotherapy. Minimal cost off set is available from carboplatin and paclitaxel.
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of pembrolizumab

Members discussed that for some patients this treatment option could provide a curative outcome.

The Group accepted the restricted local need for pembrolizumab in combination with chemoradiotherapy, for the treatment of FIGO 2014 Stage III - IVA locally advanced cervical cancer in adults who have not received prior definitive therapy, as outlined in SMC 2829.

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	FG1SMC 2829 - Pembrolizumab 25mg/mL concentrate for solution for infusion, 395mg, 790mg solution for injection (Keytruda®) is routinely available in line with national guidance (SMC 2829). **Indication under review: in combination with chemoradiotherapy (external beam radiation therapy followed by brachytherapy), for the treatment of FIGO 2014 Stage III - IVA locally advanced cervical cancer in adults who have not received prior definitive therapy.** **Pembrolizumab plus chemoradiotherapy was associated with statistically significant improvements in progression-free survival and overall survival compared with placebo plus chemoradiotherapy in patients with newly diagnosed locally advanced cervical cancer.** **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 must be initiated and supervised by specialist physicians experienced in the treatment of cancer.**	**FTEAM**

6. FORMULARY REVIEW

6.1. FORMULARY UPDATES

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

DEBRANDING

Ms Bruce reported that:

- Jardiance® film-coated tablets has been de-branded and will now be known as empagliflozin 10mg, 25mg film-coated tablets
- Trajenta® 5mg film-coated tablets has been de-branded and will now be known as linagliptin 5mg tablets
- Pentasa® 1g suppositories has been de-branded and will now be known as Mesalazine Ferring 1g suppositories
- Pentasa® 1g enema has been de-branded and will now be known as Mesalazine Ferring 1g rectal suspension

Members supported update of the formulary entries to remove the brand name, only the generic name will be noted on the formulary. **FTEAM**

DISCONTINUATIONS

Ms Bruce reported that the following medicines were being discontinued:

- chloramphenicol 250mg capsules
- hydrocortisone sodium phosphate 100mg/1mL solution for injection ampoules

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

6.2. FORMULARY UPDATES (DELEGATED AUTHORITY)

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

Ms Doney reported two instances of the Formulary Team using delegated authority to update the formulary between meetings.

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ANDEXANET ALFA 200MG POWDER FOR SOLUTION FOR INFUSION (ONDEXXYA®)

Andexanet alfa is included on the formulary for use in adults when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding treated with a direct factor Xa inhibitor, in line with its licensed indication for apixaban and rivaroxaban, and previously included off-label use for edoxaban.
The Lead Pharmacist for Haematology requested removal of the off-label indication following publication of 'Use of andexanet alfa: A British Society for Haematology position statement'.
One of the recommendations in the statement is that "If andexanet alfa is to be given, clinicians should ensure that it is only administered within its licensed indication. (1A)".

On 21/05/2026, the Formulary Team, under delegated authority, removed the off-label use for reversal of edoxaban from the formulary.

XAILIN® EYE GEL

Xailin® eye gel was previously manufactured by a different manufacturer and contained perborate as a preservative, with packaging stating it was 'preservative-free in the eye'. Following transfer to the current manufacturer, the excipient profile has changed (now containing cetrimide), and Xailin® eye gel can no longer be considered preservative-free or 'preservative-free in the eye'. The current manufacturer's website makes no claim of preservative-free status.

On 04/06/2026, the Formulary Team, under delegated authority, removed Xailin® eye gel from 'preservative free' treatment options for dry eyes.

The Group ratified the decisions taken under delegated authority. **FTEAM**

7. PUBLISHED ADVICE

7.1. SCOTTISH MEDICINES CONSORTIUM ADVICE PUBLISHED JUNE 2026

The Group noted the SMC advice published June 2026.

Following publication of the negative SMC recommendation for ataluren (Translarna®▼ - SMC 2827) and the non-submission statements for Akeega® (niraparib/abiraterone - SMC 2942), darolutamide (Nubeqa® - SMC 2940), nintedanib (Ofev® - SMC 2941) and tafasitamab (Minjuvi®▼ - SMC 2943) 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 2851 dupilumab (Dupixent®)
- SMC 2843 odevixibat (Bylvay®▼) (submission expected)
- SMC 2872 semaglutide (Wegovy®▼)
- SMC 2847 sparsentan (Filspari®▼) (submission received)
- SMC 2863 talquetamab (Talvey®▼) (submission received)

Local advice for these medicines and indications will be included in the June 2026 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'. **FTEAM**

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SMC 2861 - CAPSAICIN 179MG CUTANEOUS PATCH (QUTENZA®)

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

Ms Doney reported that:

- in December 2018 the Group:
  - supported the restricted local need for capsaicin 8% patch for peripheral neuropathic pain in diabetic and non-diabetic patients, use was limited to the Pain Clinic
  - accepted the management of patients with peripheral neuropathic pain can be challenging and that Qutenza® provides a licensed treatment option
  - accepted that use within the confines of a local protocol was unlikely to cause harm, but had the potential to provide a health gain for a small group of NHS Grampian patients. Additionally it provides specialists in the management of neuropathic pain with another treatment option of low dependence potential.
- Qutenza® was restricted to use within the Pain Clinic because:
  - the patch should be applied by a physician (or by a health care professional under the supervision of a physician), and
  - the patch requires specific precautions to be taken before handling or administering - there is a risk of occupation exposure (causing skin, eye and/or respiratory tract irritation) particularly during patch application and removal

The Group ratified SMC 2861, which aligns with current prescribing practice.

SMC 2861 - Capsaicin 179mg cutaneous patch (Qutenza®) is routinely available in line with local guidance.
Indication: alone or in combination with other medicinal products for the treatment of painful diabetic peripheral neuropathy in adults who have not achieved adequate pain relief from, or have not tolerated, conventional first- and second-line treatments.
In a double-blind, phase III study, capsaicin cutaneous patch, compared with placebo, significantly improved average daily pain score by a small amount in patients with painful diabetic peripheral neuropathy.
SMC has previously accepted capsaicin for treatment of peripheral neuropathic pain in non-diabetic adults (SMC 673/11). This advice remains valid.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only.
The Qutenza® cutaneous patch should be applied by a physician or by a health care professional under the supervision of a physician. **FTEAM**

8. PROVISIONAL ADVICE

8.1. SCOTTISH MEDICINES CONSORTIUM ADVICE ISSUED JUNE 2026

The Group noted the SMC provisional advice issued June 2026.

If the SMC issues negative recommendations or non-submission statements next month, these medicines will not be included on the formulary for the specified indications.

9. OTHER BUSINESS

9.1. FORMULARY GROUP ANNUAL REPORT

The Chair reported that Ms Doney will send out the Formulary Group Annual Report within the next few weeks. **FD**

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10. DOCUMENTS FOR INFORMATION

Items 10.1 (MHRA Safety Round-up May 2026), 10.2 (Acute and Mental Health Medicines Safety Group meeting minutes – December 2025), 10.3 (Acute and Mental Health Medicines Safety Group meeting minutes – February 2026), 10.4 (Grampian Primary Care Prescribing Group meeting minutes – March 2026), and 10.5 (Antimicrobial Management Team meeting minutes – March 2026) were noted without further comment.

11. AOCB

None.

DATE OF NEXT MEETING

Tuesday 18 August 2026 starting at 14.30 via Microsoft Teams.

Signature on file

CHAIR'S SIGNATURE **Dr Louise Elliot** **DATE** **18 August 2026**