NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 19 December 2023 at 14:30 via Microsoft Teams

PRESENT	APOLOGIES	APPROVED
Miss R Anderson	Ms L Cameron	
Dr V Chieng	Mrs S Howlett	
Dr D Culligan	Dr M Metcalfe (Vice-Chair)	
Ms A Davie		
Ms F Doney (Vice-Chair, chaired the meeting)		
Dr L Elliot (Chair, attended the meeting but unable to chair due to IT issues)		
Mrs G McKerron until item 8.3		
Mrs E Milne		
Mr M Paterson		
Mr R Sivewright		

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

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	WELCOME The Chair welcomed members, opened the meeting, and noted that a quorum was present.	
1.	**APOLOGIES** Apologies for absence were requested and noted.	
2.	**DRAFT MINUTE OF THE MEETING HELD 21 NOVEMBER 2023** The Group accepted the draft note of the meeting subject to minor typographical changes. The corrected final approved minute will be in the public domain within 21 days of final approval.	**FD**
3.	**PRESENTATION/DISCUSSION** None.	
4.	**MATTERS ARISING**	
4.1.	**ACTION LOG** The action log was noted. No additional items were identified for discussion at the meeting.	
5.	**FORMULARY GROUP DECISIONS NOVEMBER 2023 - PUBLISHED 04/12/2023** Members ratified the decisions of the November 2023 meeting as published.	
6.	**FORMULARY REVIEW**	
6.1.	**AZATHIOPRINE TABLETS** The Chair confirmed that colleagues highlighted an error with the formulary classification of azathioprine tablets. The classification for use in gastroenterology was Amber 2 compared with Amber 1 for its use in Dermatology or Rheumatology. Azathioprine is subject to a Shared Care	

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Arrangement, and the formulary classification should be the same across all indications. The error was corrected on the formulary website. However, on checking the formulary entry Mrs Standen noted the same error with the methotrexate entry [for use in gastroenterology]. The Formulary Team will correct the methotrexate entry to bring the formulary classification in line with its use in other areas. **FTEAM**

6.2. PIRFENIDONE FILM-COATED TABLETS (IDIOPATHIC PULMONARY FIBROSIS (IPF))

Dr Culligan declared a personal, non-specific interest in relation to this medicine.

The Group considered the request for pirfenidone film-coated tablets for the treatment of idiopathic pulmonary fibrosis (IPF) to include patients with a predicted forced vital capacity (FVC) >80%.

The Group noted that:

- IPF is a chronic, progressive, fibrosing interstitial lung disease of unknown etiology, and prognosis of survival is poor
- the antifibrotic drugs pirfenidone and nintedanib are licensed for the treatment of patients with IPF
- pirfenidone, as the reference product Esbriet®, was previously accepted for use in IPF patients with a FVC ≤80% - SMC 835/13 (Aug 2013)
- nintedanib, as Ofev®, is available for IPF patients with a:
  - FVC ≤80% - SMC 1076/15 (Oct 2015)
  - FVC >80% - SMC 2513 (March 2023)
- pirfenidone is now available generically
- generic medicines are considered outwith remit for SMC, so extending the use of pirfenidone to include patients with a FVC greater than 80% will not be assessed nationally
- studies show that both antifibrotic drugs have a positive effect of FVC decline, and indirect analyses suggest that patient-related outcomes, mortality, hospitalisation etc., do not differ between pirfenidone and nintedanib
- introduction will not significantly affect patient numbers, but will give clinicians a cost-effective first-choice for patients where pirfenidone is an appropriate treatment option, and a treatment option for patients with a FVC greater than 80% that are ineligible for nintedanib

Members reiterated that where two (or more) drugs in the same class are appropriate, clinicians should choose the option with the lowest acquisition cost, and pirfenidone should be considered the first-choice antifibrotic for IPF. The formulary website will be updated to highlight pirfenidone as the first-choice antifibrotic. **FTEAM**

The Group accepted the restricted local need for pirfenidone as licensed for the treatment of IPF, without the need for a full submission.

SBAR - Pirfenidone 267mg, 801mg film-coated tablets is routinely available in line with local guidance.
Indication under review: in adults for the treatment of idiopathic pulmonary fibrosis (IPF).
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 specialist physicians experienced in the diagnosis and treatment of IPF. **FTEAM**

6.3. EPIMAX® EMOLLIENT

The Chair confirmed that there has been a cluster of reports in Scotland, concerning eye-related injuries sustained by patients, following the use of some products from the Epimax® range on the skin around the eyes.

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The Chair reported that Ms Cameron has previously included information in MEDwatch regarding the potential risks of using alcohol hand gel prior to applying emollients, and information from a Field Safety Notice regarding some Epimax® products.

The Chair confirmed that Epimax® is currently noted as a first-choice emollient on the formulary.

Members supported deferring the discussion to the January meeting, when potentially Ms Cameron will be in attendance and to allow information to be collated.
Pending review in January the Group requested that the relevant Epimax® products are no longer considered first-line choices on the formulary. **FTEAM**

7. OTHER BUSINESS

None.

8. NEW PRODUCT REQUESTS

8.1. FG1SMC 2584 - CEMIPLIMAB (CUTANEOUS SQUAMOUS CELL CARCINOMA (CSCC))

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

The Group considered the SMC advice for cemiplimab as monotherapy for the treatment of adults with metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC) who are not candidates for curative surgery or curative radiation.

The Group noted that:

- in 2020, cemiplimab had a Conditional Marketing Authorisation and following a full submission considered under the end of life and orphan equivalent process, cemiplimab was accepted for interim use* in NHS Scotland, subject to ongoing evaluation and future reassessment by SMC
- July 2020, cemiplimab was included on the formulary
- cemiplimab:
  - now has a full marketing authorisation
  - [for this indication] meets SMC end of life and orphan equivalent criteria, and was accepted for use in NHS Scotland following reassessment under the end of life and orphan equivalent 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 SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of cemiplimab
- the only change identified between the interim advice and the reassessment is a change in the PAS for cemiplimab
- costs are already in the system and continued access will not affect patient numbers
- no significant service implications are expected, as cemiplimab is already widely used as the standard of care for this indication within NHS Scotland

The Group accepted the continued restricted local need for cemiplimab as monotherapy for the treatment of adults with metastatic or locally advanced CSCC who are not candidates for curative surgery or curative radiation, in line with SMC 2584.

* The 'interim acceptance' category applies to conditional licences and allows the MAH to gather more data on the medicines effectiveness prior to a reassessment by SMC. This new decision category is in line with changes in SMC process introduced Summer 2018, see SMC website for more information - https://www.scottishmedicines.org.uk/how-we-decide/interim-acceptance-decision-option/.

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	SMC 2584 - Cemiplimab 350mg concentrate for solution for infusion (Libtayo®) ▼ is routinely available in line with national guidance (SMC 2584). **Indication under review: as monotherapy for the treatment of adults with metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC) who are not candidates for curative surgery or curative radiation.** **In a phase II study of cemiplimab in patients with metastatic or locally advanced CSCC the objective response rate was 45%.** **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.** **All prescribers of should be familiar with the educational materials and inform the patients about the Patient Alert Card explaining what to do should they experience any symptom of immune-mediated adverse reactions and infusion-related reactions. The physician will provide the Patient Alert Card to each patient.**	**FTEAM**

8.2. FG1SMC 2604 - DAROLUTAMIDE (METASTATIC HORMONE-SENSITIVE PROSTATE CANCER)

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

The Group considered the request for the use of darolutamide, in combination with docetaxel and androgen deprivation therapy (ADT), for the treatment of adults with metastatic hormone-sensitive prostate cancer (mHSPC).

The Group noted that:

- darolutamide:
  - is taken at a dose of 600mg twice daily, and the first of six cycles of docetaxel should be administered within 6 weeks after the start of darolutamide
  - should be continued until disease progression or unacceptable toxicity even if a cycle of docetaxel is delayed, interrupted, or discontinued
  - [for this indication] meets SMC orphan equivalent criteria, and was accepted for use in NHS Scotland following a resubmission 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 ARASENS study only included 'fitter' patients - Eastern Cooperative Oncology Group (ECOG) performance score of 0 or 1
- in the ARASENS study:
  - the median overall survival was not reached and 48.9 months for the darolutamide and placebo groups respectively
  - the Kaplan-Meier estimated overall survival at 48 months was 63% and 50% (respectively)
  - patients in the darolutamide group had similar rates of adverse events to the placebo group
- the service anticipates use in fitter patients with higher volume, higher grade disease
- the introduction of darolutamide plus docetaxel and ADT will result in increased administration of parenteral chemotherapy as the alternatives are oral agents
- some cost off-set is available from displacement of abiraterone plus prednisolone and ADT or enzalutamide plus ADT
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of darolutamide
- the combination may potentially be more effective than the alternatives [enzalutamide/ADT or abiraterone/prednisolone/ADT] but there are no direct head-to-

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head data to support this

Members discussed the difficulty of comparing treatments when no head-to-head data is available, and indirect comparisons may not demonstrate superiority. Members supported the service's anticipated use in fitter patients with higher volume, higher grade disease.

The Group accepted the restricted local need for darolutamide plus ADT and docetaxel for the treatment of adults with mHSPC, as outlined by the service.

SMC 2604 - Darolutamide 300mg film-coated tablets (Nubeqa®) ▼ is routinely available in line with national guidance (SMC 2604).
Indication under review: treatment of adults with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel.
Darolutamide plus androgen deprivation therapy (ADT) and docetaxel significantly improved overall survival compared with placebo plus ADT and docetaxel in adults with mHSPC.
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 specialist physician experienced in treatment of prostate cancer. **FTEAM**

8.3. FG1SMC 2582 - DURVALUMAB (BILIARY TRACT CANCER)

Mr Paterson declared a personal, non-specific interest in relation to this medicine.

The Group considered the request for durvalumab in combination with gemcitabine and cisplatin for the first-line treatment of adults with locally advanced, unresectable, or metastatic biliary tract cancer.

The Group noted that:

- durvalumab:
  - [for this indication] the recommended dose is 1,500mg in combination with gemcitabine and cisplatin every three weeks for up to eight cycles, followed by 1,500mg every four weeks as monotherapy until disease progression or unacceptable toxicity.
  - [for this indication] meets SMC end of life and orphan equivalent criteria, and was accepted for use in NHS Scotland following reassessment under the end of life and orphan equivalent medicine process, the output from the PACE process, and application of SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios
  - is the first programmed cell death ligand 1 (PD-L1) inhibitor licensed for the first-line treatment of adults with locally advanced, unresectable or metastatic biliary tract cancer
- in TOPAZ-1:
  - only patients with an ECOG performance score of 0 or 1 were recruited
  - the addition of durvalumab to standard of care chemotherapy, gemcitabine plus cisplatin, improved the median overall survival by 1.5 months at the latest data cut-off
  - immune-related adverse events of special interest occurred at higher rates in the durvalumab group compared with placebo, 13% versus 4.7%
  - the median duration of treatment with durvalumab was 7.3 months (0.1 to 24.5

months)
- durvalumab continues (every 4 weeks) after chemotherapy finishes. This and the resource to manage immunotherapy-associated adverse events may have service implications, although patient numbers are expected to be small.
- this will be a new cost as durvalumab is added to current chemotherapy treatment with gemcitabine and cisplatin
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of durvalumab

Members discussed the improvement of 1.5 months in overall survival in the context of the additional cost of durvalumab. Members accepted the potential complexity of pricing arrangements for medicines, and requested information regarding the financial governance systems that are in place to support Health Technology Assessments. Information will be presented at a future meeting. **FD**

The Group accepted the restricted local need for durvalumab, in combination with gemcitabine and cisplatin, for the first-line treatment of adults with locally advanced, unresectable, or metastatic biliary tract cancer, in line with SMC 2582.

SMC 2582 - Durvalumab 50mg/mL concentrate for solution for infusion (Imfinzi®)▼ is routinely available in line with national guidance (SMC 2582).
Indication under review: in combination with gemcitabine and cisplatin for the first-line treatment of adults with locally advanced, unresectable, or metastatic biliary tract cancer.
In a phase III study, addition of durvalumab to current standard of care chemotherapy significantly improved overall survival and progression-free survival in adults receiving first-line treatment for advanced or metastatic biliary tract 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.
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 a physician experienced in the treatment of cancer. **FTEAM**

8.4. FG1SMC 2534 - RISANKIZUMAB (MODERATE TO SEVERE CROHN'S DISEASE)

Dr Culligan declared a personal, non-specific interest in relation to this medicine.

The Group considered the request for risankizumab for the treatment of patients 16 years and older with moderately to severely active Crohn's disease who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy, or if such therapies are not advisable.

The Group noted that:
- risankizumab:
  - is a monoclonal antibody that blocks the activity of IL-23 (Interleukin-23)
  - is given at a recommended dose of 600mg intravenously at week 0, 4 and 8, followed by 360mg administered by subcutaneous (SC) injection at week 12 and every 8 weeks thereafter
- in the clinical trials, the primary outcomes for placebo vs risankizumab were:
  - ADVANCE (at 12 weeks) - clinical remission 22% vs 43%; endoscopic response 12% vs 40%
  - MOTIVATE (at 12 weeks) - clinical remission 19% vs 35%; endoscopic response

11% vs 29%
- FORTIFY (at 52 weeks) - clinical remission 40% vs 52%; endoscopic response 22% vs 47%

- SC risankizumab is delivered by a single-use on-body injector with a prefilled cartridge. The on-body injector contains silver oxide-zinc batteries and microchips.
- the service plans to supply risankizumab via a homecare arrangement
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of risankizumab
- cost-offset will be available as risankizumab will be used as an alternative to vedolizumab, ustekinumab, adalimumab, infliximab or upadacitinib

Members queried the disposal arrangements for the battery and chip included in the SC on-body injector. The Chair will confirm the provisions included in the homecare arrangement. **FD**

The Group accepted the restricted local need for risankizumab, as an additional interleukin inhibitor, for the treatment of patients 16 years and older with moderately to severely active Crohn's disease, in line SMC 2534.

SMC 2534 - Risankizumab 600mg concentrate for solution for infusion, 360mg solution for injection (Skyrizi®) ▼ is routinely available in line with national guidance (SMC 2534).
Indication under review: for the treatment of patients 16 years and older with moderately to severely active Crohn's disease who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy, or if such therapies are not advisable.
Risankizumab offers an additional treatment choice in the therapeutic class of interleukin inhibitor in this setting.
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.
Risankizumab is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of conditions for which risankizumab is indicated. **FTEAM**

8.5. FG1SMC 2541 -TEZEPELUMAB (SEVERE ASTHMA)

Mr Paterson declared a personal, non-specific interest in relation to this medicine.

The Group considered the request for a new monoclonal antibody, tezepelumab, as an add-on maintenance treatment in a sub-group of adults and adolescents (12 years and older) with severe asthma.

The Group noted that:
- tezepelumab is the first monoclonal antibody to target thymic stromal lymphopoietin (TSLP) which works early in the asthma inflammatory cascade and may have a broader effect than targeting individual cytokines making it suitable for more patients
- the recommended dose is 210mg by SC injection every 4 weeks, and patients can self-inject after training in SC injection
- in NAVIGATOR, the annualised rate of asthma exacerbations (AAER) over the 52 week treatment period was 0.93 for tezepelumab and 2.10 for placebo
- tezepelumab may reduce the need for or dose of oral corticosteroids, but when assessed in the SOURCE study, the difference between tezepelumab and placebo did not reach statistical significance
- in DESTINATION (long term extension study), the AAER ratio over 104 weeks was

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0.42 in patients recruited from NAVIGATOR and 0.61 in patients recruited from SOURCE

- DESTINATION raised unexpected safety issues with an imbalance in serious cardiac events and deaths. Despite a lack of known biological explanation and no established causal relationship between tezepelumab and these events, this cannot be ruled out. The company will conduct a post-authorisation safety study to further define the safety profile of tezepelumab.
- costs will be cumulative as treatment is potentially given long term
- there is a small number of patients currently waiting to start treatment with tezepelumab
- usage may be higher in the first year due to switching from other biologics due to the limited treatment response to previous biologic treatments as well as patient acceptability
- tezepelumab would target asthma patients who do not fulfil phenotypic criteria posed by other biologic therapy and hence would be a new treatment option used as the first-line treatment in this group of patients

Although licensed from 12 years the paediatric service does not see an immediate need for tezepelumab but would support having it available for the paediatric population should there be a local need in the future.

Members raised concerns about the imbalance in serious cardiac events highlighted [with the use of tezepelumab] in the long-term extension study. Members discussed the potential for a lack of correlation between adverse cardiac events and the use of tezepelumab, particularly for colleagues in Primary Care as treatment is supplied by the managed service or via homecare.
Members queried what information would be shared with patients and with colleagues in Primary Care about this risk, and how this would be done.

Members discussed the importance of adverse drug reaction (ADR) reporting, and that prescribers, non-prescribers and patients should be aware of the reporting mechanisms.
Members assumed that the severe asthma clinic would be managed by nursing staff, and was unsure if all nurses would be independent prescribers.
Members questioned how the service plans to monitor patients, and if the monitoring [for tezepelumab] would differ because of the potential risk of cardiac adverse events.

Mindful of the imbalance in serious cardiac events and deaths shown in the long-term extension study, the Group deferred decision-making pending clarification of how these risks will be managed by the service. **FTEAM**

Points for clarification:

- the Group was unsure if all severe asthma clinic staff would be prescribers. How will the potential risk of cardiac adverse events with this new medicine be highlighted to all staff?
- what does the service plan to do to monitor patients taking tezepelumab? Is it different to the other agents used [would patients have a cardiovascular risk assessment before treatment]?
- to support recognition of a possible cardiac ADR what information, and how will the information about the risk of cardiac adverse events be shared with patients/relatives/carers and also colleagues in Primary Care?
- is the process for ADR reporting highlighted to staff and patients/relatives/carers?

Decision-making was deferred to a future meeting. **FTEAM**

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8.6. SBAR - SAPROPTERIN DIHYDROCHLORIDE (ADJUNCTIVE TREATMENT OF PHENYLKETONURIA)

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

The Group considered the request for formulary inclusion of generic sapropterin for the treatment of hyperphenylalaninaemia (HPA) in adults and paediatric patients.

The Group noted that:

- sapropterin is now available generically and generic medicines are considered outwith remit for the SMC
- sapropterin is indicated for the treatment of hyperphenylalaninaemia (HPA) in adults and paediatric patients of all ages with:
  - phenylketonuria (PKU) who have been shown to be responsive to such treatment
  - tetrahydrobiopterin (BH4) deficiency who have been shown to be responsive to such treatment
- PKU is a rare genetic disorder, where the amino acid phenylalanine cannot be broken down and accumulates in the body. High levels of phenylalanine are extremely toxic to the brain and untreated PKU causes profound brain damage resulting in very low IQ, seizures, muscle stiffness, autism, and persistent behavioural problems. In pregnancies of women with PKU, the foetus can be affected by high levels of phenylalanine.
- since PKU damage is caused by high levels of phenylalanine, non-drug treatment is a very strict low phenylalanine diet. An artificial protein mix, with added vitamins and minerals, is taken throughout the day but patients often find this unpleasant.
- sapropterin as the reference product Kuvan® is not recommended for use in NHS Scotland [SMC 558/09]
- the generic products have shown non-inferiority to the reference product Kuvan®
- sapropterin is available as Hospital-only packs, so is not prescribed in Primary Care
- cost-effectiveness is supported by Health Technology Assessment NICE TA729, and the English Commissioning position which accepted use for the full licence
- sapropterin is subject to a confidential contract agreement that improves the cost-effectiveness of treatment
- in Scotland the care of patients (adults and children) is provided by the Scottish Inherited Metabolic Disorders (SIMD) Service
- the SIMD service has considered the available evidence and the technology appraisal and judges it to be equally applicable to Scottish patients, and would like to be able to prescribe sapropterin in line with UK best practice guidance (BIMDG). Each patient will be assessed for suitability.
- acceptance to formulary would remove the need for colleagues to submit individual patient requests (PACS/IPTR applications), and helps ensure consistency of approach and avoid inequity of access across Scotland

The Group considered that the recommendations of SMC 558/09 were no longer extant and accepted the restricted local need for sapropterin without the need for a full submission, restricted to use in line with the recommendations of the SIMD Service.

SBAR - Sapropterin dihydrochloride is routinely available in line with national guidance (SIMD Service/BIMDG).
Indication under review: for the treatment of hyperphenylalaninaemia (HPA) in adults and paediatric patients of all ages with:
- phenylketonuria (PKU) who have been shown to be responsive to such treatment
- tetrahydrobiopterin (BH4) deficiency who have been shown to be responsive to such treatment
Restriction: in line with the recommendations of the Scottish Inherited Metabolic Disorders Service and UK best practice guidance (BIMDG).
It was classified 1b - available for restricted use under specialist supervision and

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8b - recommended for hospital use only.
Treatment with sapropterin dihydrochloride must be initiated and supervised by a physician experienced in the treatment of PKU and BH4 deficiency.
Active management of dietary phenylalanine and overall protein intake while taking this medicinal product is required to ensure adequate control of blood phenylalanine levels and nutritional balance. As HPA due to either PKU or BH4 deficiency is a chronic condition, once responsiveness is demonstrated, sapropterin dihydrochloride is intended for long-term use. **FTEAM**

9. PROVISIONAL ADVICE ISSUED DECEMBER 2023

9.1. SMC ADVICE ISSUED DECEMBER 2023

The Group noted the SMC provisional advice issued December 2023.

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

10. ADVICE PUBLISHED DECEMBER 2023

10.1. SMC ADVICE PUBLISHED DECEMBER 2023

The Group noted the SMC advice published December 2023.

Following publication of the non-submission statements, for amivantamab (Rybrevant®)▼ SMC 2638, lumasiran (Oxlumo®)▼ SMC 2639 and osilodrostat (Istruisa®)▼ SMC 2640, 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 2616 bimekizumab (Bimzelx®)▼ (submission received)
- SMC 2606 cipaglucosidase alpha (Pombiliti®)▼
- SMC 2625 degarelix (Firmagon®) (submission received)
- SMC 2581 deucravacitinib (Sotyktu®)▼
- SMC 2619 nivolumab (Opdivo®) (submission expected)
- SMC 2608 trastuzumab deruxtecan (Enhertu®)▼ (submission received)

Local advice for these medicines and indications will be included in the November 2023 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'. **FTEAM**

11. GENERAL INFORMATION FROM SCOTTISH MEDICINES CONSORTIUM - DECEMBER 2023

The Chair reported that due to an administrative error the SMC advice published 9 October 2023 for fenfluramine oral solution (Fintepla®) has been re-issued and updated on the SMC website.
The October document did not detail the restriction on use on the front page (as add-on therapy for treating seizures associated with Dravet syndrome where seizures have not been controlled in people aged 2 years and older after trying two or more antiseizure medicines).
A submission is expected and the updated document has been issued to colleagues in the paediatric service.

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12. DOCUMENTS FOR INFORMATION

Items 12.1 (Drug Safety Update November 2023), 12.2 (National Patient Safety Alert – insulin degludec (Tresiba®)), 12.3 (MEDwatch Vol 4. Issue 5: December 2023), 12.4 (Antimicrobial Management Team minute September 2023) and 12.5 (Grampian Primary Care Prescribing Group minute September 2023) were noted.

13. AOCB

EXTENDED USE BEYOND LABELLED EXPIRY DATE FOR SELECTED LOTS OF JEXT® ADRENALINE AUTO-INJECTORS

The Chair confirmed that a link to a recent press release would be included on the formulary entry for Jext® - https://statics.teams.cdn.office.net/evergreen-assets/safelinks/1/atp-safelinks.html.
Due to the current UK shortage of Jext® there has been agreement to extend the use of specific batch numbers of Jext® auto-injectors beyond the labelled expiry date [by two months]. Healthcare professionals should inform patients and carers of this change

THANK YOU AND GOODBYE

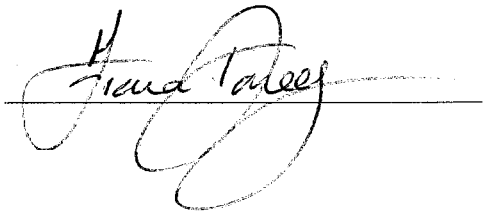
The Chair confirmed that this was Ms Anderson's last meeting, as Mrs O'Beirne is expected to return to work in January.
The Chair thanked Ms Anderson for all of her work within the Group, her input will be missed. Members wished her all the best for the future.

MEETING DATES FOR 2024

The Chair confirmed that meeting dates for 2024 were issued by email prior to the meeting and that diary invites will be issued in the next few weeks.

DATE OF NEXT MEETING

Tuesday 16 January 2024 starting at 14.30 via Microsoft Teams

CHAIR'S SIGNATURE  **DATE 16 JANUARY 2024**