NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 16 January 2024 at 14:30 via Microsoft Teams

PRESENT	APOLOGIES	APPROVED
Mrs J Barnard (for Mrs McKerron)	Mrs S Howlett	
Ms L Cameron	Mrs G McKerron	
Dr V Chieng	Dr M Metcalfe (Vice-Chair)	
Dr D Culligan		
Ms A Davie		
Ms F Doney (Vice-Chair)		
Dr L Elliot (Chair)		
Mrs E Milne		
Mrs S O'Beirne		
Mr M Paterson (from item 7.2)		
Mr R Sivewright		

IN ATTENDANCE

Ms Dawn Bruce, Specialist Pharmacy Technician, Formulary Team
Mrs Fiona Raeburn, Specialist Pharmacist in Substance Use, for item 3
Mrs Christine Standen, Formulary and Medicines Management Pharmacist

OBSERVERS

Dr Karen Simpson, Insch Medical Practice GP, Garioch Cluster quality lead
Mrs Birgit Teismann, Advanced Primary Care Clinical Pharmacist and Team Co-Ordinator Aberdeen City Health and Social Care Partnership (ACHSCP)

Note: some items were taken outwith agenda order.

ITEM	SUBJECT	ACTION
	WELCOME	
	The Chair welcomed members, opened the meeting, and noted that a quorum was present.	
	The Chair welcomed Mrs June Barnard, Chief Nurse Acute, who was deputising for Mrs McKerron.	
	The Chair introduced two observers, Dr Karen Simpson, a GP in Insch Medical Practice and Garioch Cluster quality lead who was observing with a view to becoming a new GP representative, and Mrs Birgit Teismann, Advanced Primary Care Clinical Pharmacist and Team Co-Ordinator ACHSCP, who was observing with a view to becoming a deputy for the City Primary Care Lead Pharmacist.	
1.	**APOLOGIES**	
	Apologies for absence were requested and noted.	
2.	**DRAFT MINUTE OF THE MEETING HELD 19 DECEMBER 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**

ITEM	SUBJECT	ACTION

4. MATTERS ARISING

4.1. ACTION LOG

The action log was noted.

No additional items were identified for discussion at the meeting.

4.2. EPIMAX® EMOLLIENT

Ms Doney provided members with an update on the discussion about the 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.

Ms Doney confirmed that:
- the relevant Epimax® products are no longer noted as first-line options on the formulary
- this is a developing situation and the paper, 'Epimax-Related Ocular Surface Toxicity (EROST): the Glasgow experience', was shared with the Dermatologists
- the Dermatologists are reviewing the information and will provide feedback in the future

Mrs Cameron provided members with the background to the cluster of reports, and the timeline of the information released, including publication of local MedWatch articles.

4.3. RISANKIZUMAB SC ON-BODY INJECTOR

Ms Doney confirmed that the homecare arrangement for the risankizumab subcutaneous on-body injector includes disposal of the battery and chip.

5. FORMULARY GROUP DECISIONS DECEMBER 2023 - PUBLISHED 29/12/2023

Members ratified the decisions of the December 2023 meeting as published.

6. FORMULARY REVIEW

6.1. NIRAPARIB (ZEJULA®)

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

It was noted that:
- GlaxoSmithKline has confirmed that niraparib 100mg tablets will replace the 100mg capsules
- the tablets have been demonstrated to be bioequivalent and interchangeable
- the tablets contain less lactose than the capsules, so may be more suitable for patients with severe lactose intolerance
- the PAS paperwork has been updated to include the new formulation and the NHS list price and PAS discount is the same for both formulations
- the service has confirmed that there is still a local need for niraparib

The Group accepted the restricted local need for niraparib film-coated tablets in line with the SMC advice for the capsule formulation (including restrictions) without the need for a submission.

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Niraparib 100mg film-coated tablets (Zejula®) is routinely available in line with national guidance (SMC 1341/18, SMC 2338).
Indications under review: as monotherapy for the maintenance treatment of adults with :

1) **platinum-sensitive relapsed high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy and do not have a germline BRCA mutation – SMC 1341/18 (August 2018)**
2) **advanced epithelial (FIGO Stages III or IV) high-grade ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy – SMC 2338 (May 2021)**

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.
Treatment should be initiated and supervised by a physician experienced in the use of anticancer medicinal products. **FTEAM**

The formulary entry for niraparib 100mg hard capsules will be changed, noting that the capsules are being replaced by the film-coated tablets. **FTEAM**

6.2. NATIONAL PATIENT SAFETY ALERT: VALPROATE: ORGANISATIONS TO PREPARE FOR NEW REGULATORY MEASURES FOR OVERSIGHT OF PRESCRIBING TO NEW PATIENTS AND EXISTING FEMALE PATIENTS

Ms Doney reported that representatives from different specialties are meeting on 23 January to discuss and review Grampian's compliance with the new regulatory measures [for (oral) sodium valproate, valproic acid and valproate semisodium], and to ensure the appropriate governance is in place.

Ms Doney will provide feedback at a future meeting. **FD**

6.3. SIGN 168 Assessment, diagnosis, care and support for people with dementia and their carers

Ms Doney reported that the Scottish Intercollegiate Guidelines Network (SIGN) published SIGN 168, a clinical guideline covering the assessment, diagnosis, care and support for people with dementia and their carers. The guideline does not consider pharmacological management but points to the NICE guidance [NG97].

The Formulary Team will liaise with colleagues to confirm the formulary is in line with the recommendations of NG97 and bring information back to a future meeting. **FTEAM**

6.4. DERMATOLOGY PATHWAYS ON RDS (RIGHT DECISION SERVICE)

It was reported that the Right Decision Service (RDS) is hosting NHS Scotland dermatology pathways. The local specialists are aware of the pathways and were involved in their development.

The Formulary Team will review the information [with colleagues in dermatology] to bring the formulary in line with the RDS pathways, and link the pathways to the formulary. **FTEAM**

The Formulary Team will contact the RDS to confirm how the pathways are updated and new SMC advice is incorporated into the pathways. **FTEAM**

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7. OTHER BUSINESS

7.1. DECLARATION OF INTEREST FOR CALENDAR YEAR 2023

The Chair reminded members to complete and return their annual declaration of interest form for 2023. **ALL**

7.2. NICE AND SMC COLLABORATION ON MTA FOR CYSTIC FIBROSIS

Ms Doney reported that SMC and NICE are collaborating on a multiple technology appraisal for the cystic fibrosis drugs [ivacaftor–tezacaftor–elexacaftor, tezacaftor–ivacaftor and lumacaftor–ivacaftor].

Further updates and timelines are expected in January.

7.3. UPPER GI BEST PRACTICE CONSENSUS STATEMENT – (TO IMPROVE MUCOSAL VISUALISATION USING SIMETHICONE (SURFACTANT) +/- N-ACETYLCYSTEINE (MUCOLYTIC)

Ms Doney summarised information from the Gastroenterology Service regarding the use of two medicines, Infacol® (simethicone) and N-acetylcysteine, as physical agents to improve the quality of endoscopy mucosal views.

Ms Doney proposed that a full submission was not required for the single-dose off-label use of these products for improved visualisation of a procedure.

Ms Doney confirmed that:

- Infacol® is currently non-formulary for its licensed indication, and as a General Sales List (GSL) product it is strictly speaking outwith remit for the Formulary Group
- the service plans to use single doses of simethicone with or without N-acetylcysteine in line with the Best Practice Consensus Statement. The products will be given prior to endoscopy.
- there is a drive for Health Boards to use these products prior to the procedure

Members agreed that it was not appropriate or cost-effective to request Primary Care prescriptions for these items, and it would be preferable to administer the preparations in the treatment/procedure area.

Members supported the position that this was akin to the SCOTCap Test scenario and formulary submissions were not required for the off-label use of single-doses of these products prior to endoscopy. Supply and administration should be limited to the relevant acute service area and prescription requests for Infacol® or N-acetylcysteine should not be sent to Primary Care.

Members discussed the logistics of supply, and noted that if medicines are supplied via acute pharmacy then non-formulary medicines may require additional paperwork.

Ms Doney confirmed that the governance issues [who is prescribing/administering the medicine(s) and the need for a guideline/protocol/procedure to facilitate this] were discussed with the Associate Director of Pharmacy and will be taken forward by the Medicines Guidelines and Policies Group (MGPG).

The Medicines Information Pharmacist and Medication Safety Advisor will be copied to emails to allow them to liaise with the MGPG [and the service] regarding the practicalities of supply and administration of these medicines. **FTEAM**

7.4. FORMULARY GROUP SURVEY OUTCOMES – (PROPOSED CHANGES)

Following review of the survey results Mrs Standen summarised some proposed changes to the meetings that will be trialled for three months starting at the February meeting.

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1. Members asked for longer time to review the meeting papers.
   The main papers will be sent 14-days before the meeting, with the SMC advice and the medicines and marketing authorisation holders list following a week later.
2. The agenda order will be revised moving the medicines decision-making sections earlier on the agenda

Members supported the proposed changes to issuing the papers and the agenda order.

Members discussed the possibility of reducing the meeting schedule from 11 to 10 meetings a year by introducing a break over the festive period.
There was some support for cancelling the December meeting, but a survey will be sent to canvass opinions and allow members more time to consider the advantages and disadvantages of a change. **FTEAM**

3. REQUEST FOR RECLASSIFICATION OF BUVIDAL®

The Chair welcomed Mrs Fiona Raeburn, Specialist Pharmacist in Substance Use, to discuss the request to reclassify Buvidal® to allow prescribing in primary care on the advice of the specialist service.

Mrs Raeburn confirmed that:

- Buvidal® is a prolonged-release buprenorphine injection
- the service is looking to transfer some Buvidal® prescribing to Primary Care, but only where it is supported [by the General Practice] and beneficial for patients for Buvidal® to be prescribed in Primary Care
- the financial impact of the change is being considered elsewhere
- the service is not looking for administration in General Practice. The proposal is that prescribing will be in Primary Care with administration in Community Pharmacies.
- the intent is for GPs that are confident/comfortable to prescribe Buvidal® to link with available Community Pharmacies
- the specialist service is working on a training plan for colleagues in Primary Care to ensure that where required there is education available regarding the use of Buvidal®

Mrs Raeburn answered questions from members:

- colleagues in the specialist service are working on training for Primary Care (including a training plan) and update of the local enhanced service to include Buvidal®
- the local prescribing guidance will be updated to include Buvidal®
- if Community Pharmacy administration is not available patients will be taken back into the Substance Use service clinics
- the prison service has a relatively stable Buvidal® population, and anyone coming from prison goes to their local drug and alcohol service
- when moving patients to community prescribing and administration, the service is looking to identify those that are not changing doses regularly and not requiring intensive support from community psychiatric nursing, these patients will remain within the service
- if circumstances change, as with any other patient, there is a route back into the service. This includes the opportunity to come back into the service to come off treatment.
- Sixmo® is a six-monthly implant. It is a relatively low-dose buprenorphine product, and at lower doses of buprenorphine there are more opportunities to use substances on top. It requires surgical insertion and the service is not in a position to offer this easily. The service does not wish to include Sixmo® on the formulary, but will submit a request if the situation changes.

The Chair thanked Mrs Raeburn for attending the meeting and clarifying the proposed use of Buvidal®. Mrs Raeburn left the meeting before decision-making.

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BUPRENORPHINE PROLONGED-RELEASE SOLUTION FOR INJECTION (BUVIDAL®)

There were no declarations of interest recorded in relation to this product.
Members were minded to support the proposal to reclassify Buvidal® to allow prescribing in Primary Care on the advice of the specialist service. However, to allow reclassification members agreed that the following needed to be in place:

- education and training available for prescribers in General Practice
- the LES updated to include Buvidal®
- the local buprenorphine prescribing guidance updated

The formulary classification of Buvidal® remains unchanged until confirmation of the points above. **FR/ FTEAM**

SMC 2372 - BUPRENORPHINE 74.2MG IMPLANT (SIXMO®)

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

Members supported the service's position that there is currently not a local need for the six-monthly buprenorphine implant.

SMC 2372 - Buprenorphine 74.2mg implant (Sixmo®)▼ is not routinely available as there is a local preference for alternative medicines.
Indication under review: for substitution treatment for opioid dependence in clinically stable adults who require no more than 8mg/day of sublingual buprenorphine, within a framework of medical, social and psychological treatment.
Buprenorphine implant was non-inferior to buprenorphine-naloxone sublingual tablets for controlling illicit drug use in patients transferred from stable daily doses of sublingual buprenorphine up to 8mg.
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.
Not routinely available as there is a local preference for alternative medicines. **FTEAM**

8. NEW PRODUCT REQUESTS

8.1. FG1SMC 2608 - TRASTUZUMAB DERUXTECAN (UNRESECTABLE OR METASTATIC HER2-LOW BREAST CANCER)

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

The Group considered the request for trastuzumab deruxtecan for the treatment of adults with unresectable or metastatic *HER2-low breast cancer who have received prior chemotherapy in the metastatic setting or developed disease recurrence during or within six months of completing adjuvant chemotherapy.

The Group noted that:

- trastuzumab deruxtecan:
  - is the first licensed treatment for HER2-low metastatic or unresectable breast cancer
  - is given as an intravenous infusion 5.4mg/kg once every 3 weeks until disease progression or unacceptable toxicity
  - is included on formulary as monotherapy for the treatment of adults with unresectable or metastatic HER2-positive breast cancer who have received one or more prior anti-HER2-based regimens (SMC 2545, SMC 2388)

* human epidermal growth factor receptor 2

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- [for this indication] meets SMC end of life and orphan equivalent criteria, and was accepted for use in NHS Scotland following a full submission assessed 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
- in DESTINY-Breast04:
  - the median progression-free survival (PFS) in the hormone receptor-positive cohort was 10.1 months for trastuzumab deruxtecan vs 5.4 months for physician choice of chemotherapy
  - the median PFS in the full set analysis (secondary outcome) was 9.9 months for trastuzumab deruxtecan and 5.1 months for physician choice of chemotherapy
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of trastuzumab deruxtecan
- the service states that trastuzumab deruxtecan will be used following †CDK4/6 inhibitors in patients who are hormone receptor positive, and either before or after sacituzumab govitecan in patients who are triple negative

Members discussed the financial pressure that the 'access to new medicines' agenda from Scottish Government creates for Health Boards.

The Group accepted the restricted local need for trastuzumab deruxtecan as monotherapy for the treatment of adults with unresectable or metastatic HER2-low breast cancer who have received prior chemotherapy in the metastatic setting or developed disease recurrence during or within six months of completing adjuvant chemotherapy, in line with SMC 2608.

SMC 2608 - Trastuzumab deruxtecan 100mg powder for concentrate for solution for infusion (Enhertu®) ▼ is routinely available in line with national guidance (SMC 2608).
Indication under review: as monotherapy for the treatment of adults with unresectable or metastatic HER2-low breast cancer who have received prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy.
In an open-label, randomised, phase III study, trastuzumab deruxtecan significantly improved progression-free survival compared with single-agent chemotherapy in patients with HER2-low, hormone receptor-positive, unresectable or metastatic breast cancer who had received one or two lines of prior chemotherapy in the metastatic 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.
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.
Enhertu® ▼ should be prescribed by a physician and administered under the supervision of a healthcare professional experienced in the use of anticancer medicinal products. In order to prevent medicinal product errors, it is important to check the vial labels to ensure that the medicinal product being prepared and administered is Enhertu® ▼ (trastuzumab deruxtecan) and not trastuzumab or trastuzumab emtansine.
Enhertu® ▼ should not be substituted with trastuzumab or trastuzumab emtansine. **FTEAM**

† cyclin-dependent kinase 4 and 6

8.2. FG1SMC 2399 – PEMIGATINIB (ADVANCED OR METASTATIC CHOLANGIOCARCINOMA WITH A FGFR2 FUSION OR REARRANGEMENT)

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

The Group considered the request for pemigatinib for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy.

The Group noted that:

- pemigatinib is an oral tablet, taken at a recommended dose of 13.5mg once daily for 14 days followed by 7 days off therapy. Treatment should be continued as long as the patient does not show evidence of disease progression or unacceptable toxicity.
- FGFR 2 fusion positivity status must be known prior to initiation of pemigatinib therapy. The service plan to test for FGFR2 at diagnosis.
- hyperphosphataemia is a pharmacodynamic effect expected with pemigatinib. In all patients, a low-phosphate diet should be initiated when serum phosphate level is > 5.5mg/dL and adding a phosphate-lowering therapy should be considered when level is > 7mg/dL. The dose of phosphate-lowering therapy should be adjusted until serum phosphate level returns to < 7mg/dL.
- due to the risk of serous retinal detachment, the SmPC recommends that Ophthalmological examination, including optical coherence tomography should be performed prior to initiation of therapy and every 2 months for the first 6 months of treatment, every 3 months afterwards, and urgently at any time for visual symptoms.
- data comes from FIGHT-202 study:
  - an open-label, single arm, phase II study
  - the primary outcome was the proportion of patients with FGFR2 fusions or rearrangements who achieved an objective response (best overall response of confirmed complete response or confirmed partial response) was 37% (complete response 3.7%, partial response 33%, stable disease 45%, progressive disease 15%)
  - the median duration of treatment was 15.4 months
- the company also presented [to SMC] an indirect treatment comparison of pemigatinib and mFOLFOX, favoured pemigatinib for PFS and OS, however the study populations from the two trials differed. ABC-06 (mFOLFOX trial) did not test for FGFR2 status, whereas FIGHT-202 (pemigatinib trial) only recruited patients with FGFR2 fusions or rearrangements.
- there is some evidence to suggest that patients with FGFR2 genetic alterations may have better prognosis [ref SMC]
- patient numbers are expected to be very small
- pemigatinib will be used instead of CAPOX (oxaliplatin/capecitabine) or FOLFOX (oxaliplatin/fluorouracil (5FU))
- based on drug costs there will be minimal cost offset however as pemigatinib is an oral tablet, there will be reduced inpatient admissions and reduced need for dispensing via the aseptic pharmacy service

The Group accepted the restricted local need for pemigatinib for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with a FGFR2 fusion or rearrangement that have progressed after at least one prior line of systemic therapy, as outlined in SMC 2399.

SMC 2399 - Pemigatinib 4.5mg, 9mg, 13.5mg tablets (Pemazyre®)▼ is routinely available in line with national guidance (SMC 2399).
Indication under review: for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy.
In a phase II, single-arm study, pemigatinib demonstrated anti-tumour activity in

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patients with advanced/metastatic or surgically unresectable cholangiocarcinoma with a FGFR2 fusion or rearrangement who have progressed on at least one line of prior systemic therapy.
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.
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. Therapy should be initiated by a physician experienced in the diagnosis and treatment of patients with biliary tract cancer. FGFR 2 fusion positivity status must be known prior to initiation of pemigatinib therapy. Assessment of FGFR 2 fusion positivity in tumour specimen should be performed with an appropriate diagnostic test. FTEAM

8.3. NCMAG 107 - DABRAFENIB AND TRAMETINIB (OFF-LABEL USE FOR LOCALLY ADVANCED OR METASTATIC ANAPLASTIC THYROID CANCER)

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

The Group considered the request for the off-label use of dabrafenib used in combination with trametinib for the treatment of adults with locally advanced or metastatic anaplastic thyroid cancer with evidence of a BRAF V600E mutation and with no satisfactory locoregional treatment options.

The Group noted that:

- [for this indication] the recommended dose is dabrafenib 150mg twice daily plus trametinib 2mg once daily until disease progression or unacceptable toxicity
- before taking dabrafenib plus trametinib, patients must have confirmation of tumour BRAF V600 mutation using a validated test
- the combination [of dabrafenib plus trametinib] is already included on formulary for other licensed indications, and the service has experience using this combination
- dabrafenib plus trametinib is recommended [for this indication] by NHS England in a Clinical commissioning policy
- evidence comes from ROAR:
  - an open-label, non-randomised, phase II study
  - the objective response rate (primary outcome) defined as the percentage of participants with a confirmed overall response by investigator assessment was 56% and by independent radiological review was 53%
  - only included patients with a performance status of 2 or less
- patient numbers are expected to be very small
- real world data from Lorimer et al 2022 noted the median number of treatment cycles (1 cycle = 28 days) was 4.5 with a range of 1 to 22 cycles
- dabrafenib plus trametinib will be used instead of standard chemotherapy with carboplatin plus paclitaxel or cisplatin plus doxorubicin
- the NCMAG advice takes account of confidential pricing agreements for both medicines

The Group accepted the restricted local need for the off-label use of the combination of darafenib plus trametinib for the treatment of adults with locally advanced or metastatic anaplastic thyroid cancer with evidence of a BRAF V600E mutation and no satisfactory locoregional treatment options, in line with NCMAG 107.

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	NCMAG 107 - Dabrafenib 50mg, 75mg hard capsules (Tafinlar®) plus trametinib 0.5mg, 2mg film-coated tablets (Mekinist®) are routinely available in line with national guidance (NCMAG 107). **Indication under review: [off-label] for the treatment of adults with locally advanced or metastatic anaplastic thyroid cancer with evidence of a BRAF V600E mutation and with no satisfactory locoregional treatment options.** **This advice applies only in the context of the confidential pricing agreements in NHS Scotland, upon which the decision was based, or confidential pricing agreements or list prices that are equivalent or lower.** **It was classified 3b - licensed product available for off-label use and 8b - recommended for hospital use only. Treatment with dabrafenib and trametinib should only be initiated and supervised by a physician experienced in the use of anti-cancer medicinal products. Before taking dabrafenib and trametinib, patients must have confirmation of BRAF V600 mutation using a validated test.**	**FTEAM**

9. PROVISIONAL ADVICE ISSUED JANUARY 2024 AND DECEMBER 2023

9.1. SMC ADVICE ISSUED JANUARY 2024

The Group noted the SMC provisional advice issued January 2024

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

9.2. NCMAG ADVICE ISSUED DECEMBER 2023

The Group noted the NCMAG provisional advice issued December 2023.

If the negative NCMAG recommendation is published next month, this medicine will not be included on the formulary for the indication in question.

10. ADVICE PUBLISHED JANUARY 2024

10.1. SMC ADVICE PUBLISHED JANUARY 2024

The Group noted the SMC advice published January 2024.

Following publication of the negative SMC recommendation for belantamab mafodotin (Blenrep®)▼ SMC 2597, and the non-submission statements, for axicabtagene ciloleucel (Yescarta®)▼ SMC 2646 and setmelanotide (Imcivree®)▼ SMC 2647, 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 2588 burosumab (Crysvita®)
- SMC 2589 pembrolizumab (Keytruda) ®) (submission expected)

Local advice for these medicines and indications will be included in the January 2024 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'. **FTEAM**

Ms Doney reported that SMC 2588 is the first SMC reassessment of an ultra-orphan initial assessment and next month the Formulary Team will present options for review of these reassessments. **FTEAM**

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11. GENERAL INFORMATION FROM SCOTTISH MEDICINES CONSORTIUM – JANUARY 2024

None.

12. DOCUMENTS FOR INFORMATION

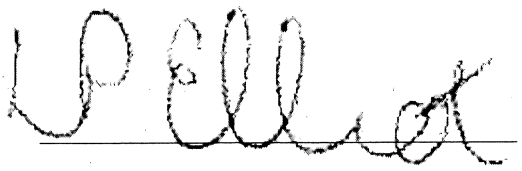
Items 12.1 (Drug Safety Update December 2023) and 12.2 (AMT minute November 2023) were noted.

13. AOCB

None.

DATE OF NEXT MEETING

Tuesday 20 February 2024 starting at 14.30 via Microsoft Teams

CHAIR'S SIGNATURE  **DATE 20 FEBRUARY 2024**