NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 21 September 2021 at 14:30 via Microsoft Teams

PRESENT	APOLOGIES	APPROVED
Ms A Davie	Dr M Metcalfe	
Ms F Doney		
Dr L Elliot		
Dr J Fitton (from item 4)		
Ms M Galvin		
Professor J McLay (Chairman)		
Mrs L Montgomery		
Mrs K Neave		
Dr J Newmark		
Mrs S O'Beirne		
Mr M Paterson		
Mr R Sivewright		

IN ATTENDANCE
Ms Christine Hay, Formulary and Medicines Management Pharmacist
Ms Lindsay Cameron, Medication Safety Advisor (observer)
Ms Rachel La Hatt, medical student (observer)

ITEM	SUBJECT	ACTION
	The Chairman welcomed members, opened the meeting and noted that a quorum was present. The Chairman welcomed Ms Lindsay Cameron and Ms Rachel La Hatt to the meeting. Ms Cameron was attending the meeting as an observer with a view to joining the Formulary Group in the near future.	
1.	**APOLOGIES** Apologies for absence were requested and noted.	
2.	**DRAFT MINUTE OF THE MEETING HELD 17 AUGUST 2021** The Group accepted the draft note of the August meeting subject to minor typographical changes.	**FTEAM**
	The corrected final approved minute will be in the public domain within 21 days of approval.	**FD**
3.	**PRESENTATION** None.	
4.	**MATTERS ARISING**	
4.1.	**ACTION LOG** The action log was noted. No additional items were identified that should have been included on the agenda.	
4.2.	**PENTOSAN POLYSULFATE SODIUM (ELMIRON®) - MATTERS ARISING FROM THE JULY 2021 MEETING** The Group noted the responses from urology regarding the queries raised at the July meeting. The Group was reassured that patients will be kept under review by the specialist service on an ongoing basis rather than defaulted to primary care.	

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Members agreed that the responses provided some assurance but there was a need for more clarity about who is responsible for ensuring that the patient has attended for eye checks, and that primary care clinicians can continue to prescribe Elmiron®.

There was a concern that people do not attend for their 2-yearly eye checks, and there was a need for a more direct and transparent communication structure to ensure the monitoring has been done, or if not, that the patient is aware that prescribing will not continue.

The Group queried:
- if the eye examination would form part of the 'usual' 2-year eye check?
- if the checks can be done by opticians, should this be done at the 'routine' eye check rather than waiting to 5 years?
- what information is available in the Elmiron® information pack for clinicians?
- if patients would be advised that if they do not attend for eye checks then prescribing will be stopped?

The Group agreed that the Consultant/specialist service is responsible for making sure that monitoring is being done and fed back to Primary Care so that prescribing is continued.

Ms Doney will liaise with Mr Lam and link with colleagues in Ophthalmology to confirm the process for ensuring patients are aware of the need for regular eye checks, and the outcome of the checks are fed back to primary care to allow ongoing prescribing of Elmiron®. **FD**

5. FORMULARY GROUP DECISIONS AUGUST 2021 - PUBLISHED 30/08/2021

Members ratified the decisions of the August 2021 meeting as published.

6. NETFORMULARY/FORMULARY REVIEW

6.1. DOAC GUIDANCE UPDATED

The Chairman reported that:
- the direct oral anticoagulant (DOAC) prescribing guidance for the prevention of stroke and systemic embolism in adults with non-valvular atrial fibrillation (NVAF) has been updated
- apixaban is now noted as the first-line DOAC for NVAF with rivaroxaban second-line
- the formulary has been updated

6.2. SUBOXONE® (BUPRENORPHINE/NALOXONE) 2MG/0.5MG, 8MG/2MG SUBLINGUAL FILM

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

The Group considered the SBAR outlining a proposal to include Suboxone® sublingual film on the formulary.

The Group noted that:
- Suboxone®:
  - is a fixed-dose combination of buprenorphine and naloxone, that is an option where there is a concern about misuse via snorting or injecting
  - as the sublingual tablet formulation, is included on the formulary (generically) as substitution treatment for opioid drug dependence. Use is in line with local prescribing guidance, restricted to those in whom methadone is not suitable and for whom the use of buprenorphine is considered appropriate.
- Suboxone® sublingual film:
  - can be taken sublingually or buccally
  - offers increased speed of dissolution compared with buprenorphine/naloxone

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sublingual tablet, which is advantageous for supervised consumption
    - is a new formulation of an existing formulary medicine, with a known adverse effect profile, and no new or additional safely signals
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of Suboxone® sublingual film
- the existing sublingual tablet formulation will remain on formulary meantime

The Group accepted the restricted local need for Suboxone® sublingual film. Formulary inclusion is subject to update of the local prescribing guidance.

SBAR SMC 2316 - Suboxone® 2mg/0.5mg, 8mg/2mg sublingual film (buprenorphine/naloxone) is routinely available in line with local guidance.
Indication under review: substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. The intention of the naloxone component is to deter intravenous misuse. Buprenorphine/naloxone is indicated in adults and adolescents over 15 years of age who have agreed to be treated for addiction.
Restriction: to those patients in whom methadone is not suitable and for whom the use of buprenorphine is considered appropriate.
Buprenorphine/naloxone sublingual film (Suboxone®) and buprenorphine/naloxone sublingual tablets (Suboxone®) deliver similar plasma concentrations of buprenorphine but are not bioequivalent. Please refer to the relevant Summary of Product Characteristics for further detail, including guidance on switching between formulations.
Generic buprenorphine sublingual tablets are available at lower cost. 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 8d - treatment may be initiated in community on the recommendation of a consultant/specialist. Treatment must be under the supervision of a physician experienced in the management of opiate dependence/addiction. **FTEAM**

6.3. MAGNESIUM KORA HEALTHCARE 4MMOL (97MG) TABLETS

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

The Group considered the SBAR outlining a request to include a new licensed oral magnesium tablet on the formulary.

The Group noted that:
- the current oral magnesium products on formulary are Magnaspartate® (magnesium aspartate) sachets and Neomag® (magnesium glycerophosphate) chewable tablets
- a new licensed tablet is available, Magnesium Kora Healthcare 4mmol (97mg) tablets
- Magnesium Kora Healthcare Tablets:
    - contain magnesium citrate equivalent to 4mmoL (97mg) of magnesium
    - are not chewable but they can be broken in half using the score line
    - are sugar-free so they may be preferable for diabetic patients
    - cost less than, and would be an alternative to, Neomag® chewable tablets
- there does not appear to be an issue with using different magnesium salts for the treatment of hypomagnesaemia

Ms Davie questioned how Magnesium Kora appeared in prescribing systems, and if it could be selected as a ‘branded’ product.
Members discussed the need to highlight the correct licensed product in prescribing systems.

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	Prescribing systems will be checked to confirm if Magnesium Kora 4mmol/L tablets is available for selection, and if possible ScriptSwitch will be used to help direct prescribing to the preferred formulations of licensed medicines.	AD/FD
	The Group accepted the restricted local need for Magnesium Kora Healthcare 4mmoL (97mg) tablets. Formulary inclusion is subject to update of the local prescribing guidance, and the use of Neomag® will be phased out before removal from the formulary. **SBAR - Magnesium Kora Healthcare 4mmoL (97mg) tablets is routinely available in line with local guidance.** **Indication under review: for the treatment and prevention of magnesium deficiency in adults, adolescents and children aged from 12 years.** **It was classified 1a - available for general use and 8e - treatment may be initiated in either Primary or Secondary care.**	FTEAM

6.4. ANTHELIOS® XL (SPF 50+ MELT-IN CREAM)

The Group noted that Anthelios® XL (SPF 50+ Melt-in cream) has been removed from the list of products available under Advisory Committee on Borderline Substances (ACBS) for photodermatoses, and the formulary entry has been updated in line with the current ACBS choices.

7. OTHER BUSINESS

7.1. FORMULARY GROUP REPORT 2020/21

The Group noted the content of the Formulary Group annual report for 2020/21.

8. NEW PRODUCT REQUESTS

8.1. FG1SMC 2349 - ATEZOLIZUMAB AND BEVACIZUMAB (HEPATOCELLULAR CARCINOMA)

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

The Group reviewed the request for atezolizumab in combination with bevacizumab used for the treatment of adults with advanced or unresectable hepatocellular carcinoma (HCC) who have not received prior systemic therapy.

The Group noted that:

- the service already has significant experience using atezolizumab and bevacizumab separately for other indications
- the licensing of atezolizumab 1,200mg differs from atezolizumab 840mg, care should be taken to select the correct strength of atezolizumab as only the 1,200mg vial is licensed for HCC
- the Summary of Product Characteristics (SmPC) for bevacizumab does not include this indication [hepatocellular carcinoma] in its therapeutic indications
- in the trial [IMBrave150]:
  - progression-free survival (PFS) for atezolizumab plus bevacizumab was 6.8 months
  - patients could discontinue either atezolizumab or bevacizumab and continue on single-agent therapy [until loss of clinical benefit or unacceptable toxicity associated with the single-agent]
- [for this indication] atezolizumab plus bevacizumab was accepted for use in NHS Scotland following the output from the PACE process, and application of the appropriate SMC modifiers
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of atezolizumab
- patient numbers will be small but will increase over the next few years
- for eligible patients, atezolizumab plus bevacizumab will be used first-line instead of the oral agents lenvatinib and sorafenib

- lenvatinib's licence restricts its use to first-line only, but it will remain on formulary for those ineligible for atezolizumab plus bevacizumab, sorafenib will move to a second-line treatment option
- there will be a degree of cost offset available from displacement of lenvatinib or sorafenib, however sorafenib will be available later in the treatment pathway

The Group accepted the restricted local need for the combination regimen atezolizumab and bevacizumab used for the treatment of adults with advanced or unresectable HCC who have not received prior systemic therapy, as outlined in SMC 2349.

SMC 2349 - Atezolizumab 1,200mg concentrate for solution for infusion (Tecentriq®) ▼ is routinely available in line with national guidance (SMC 2349).
Indication under review: in combination with bevacizumab for the treatment of adults with advanced or unresectable hepatocellular carcinoma (HCC) who have not received prior systemic therapy.
In a phase III study in patients with advanced or unresectable HCC who had not received prior systemic therapy, atezolizumab plus bevacizumab was associated with greater overall and progression-free survival compared with a multikinase inhibitor.
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. Atezolizumab must be initiated and supervised by physicians experienced in the treatment of cancer. **FTEAM**

8.2. FG1SMC 2329 – LONSURF® (GASTRIC CANCER)

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

The Group reviewed the request for the fixed-dose combination tablet Lonsurf® as a third-line treatment for adults with metastatic gastric cancer including adenocarcinoma of the gastroesophageal junction.

The Group noted that:

- Lonsurf®:
  - is an oral cytotoxic tablet containing two active substances trifluridine and tipiracil
  - [for this indication] meets SMC orphan equivalent and end of life criteria, and was accepted for restricted use in NHS Scotland following the output from the PACE process, and application of the appropriate SMC modifiers
  - [for this indication] is not recommended by the National Institute for Health and Care Excellence (NICE) as the most plausible cost-effectiveness estimate is much higher than what NICE normally considers an acceptable use of NHS resources
- the Phase III study [TAGS] only included patients with an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. The median duration of exposure to treatment in the Lonsurf® group was 6.7 weeks and 5.7 weeks in the placebo group. Overall survival for Lonsurf® was 5.7 months compared to 3.6 months for placebo.
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of Lonsurf®
- patient numbers are expected to be very small
- this will be a new cost to the service as there are no standard third-line treatment options for metastatic gastric cancer

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The Group accepted the restricted local need for Lonsurf® tablets as a third-line treatment for adults with metastatic gastric cancer, as outlined in SMC 2329.

SMC 2329 - Lonsurf® 15mg/6.14mg, 20mg/8.19mg film-coated tablets (trifluridine/tipiracil) is routinely available in line with national guidance (SMC 2329).
Indication under review: monotherapy as a third-line treatment for adults with metastatic gastric cancer including adenocarcinoma of the gastroesophageal junction.
In a phase III, randomised, double-blind study, trifluridine/tipiracil was associated with an improvement in overall survival compared with placebo.
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. Lonsurf® should be prescribed by physicians experienced in the administration of anticancer therapy. **FTEAM**

8.3. FG1SMC 2283 - TRABECTEDIN (SOFT TISSUE SARCOMA)

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

The Group considered the request for trabectedin monotherapy for the treatment of adults with advanced soft tissue sarcoma.

The Group noted that:

- trabectedin:
  - [for this indication] was previously not recommended for use in NHS Scotland
  - [for this indication] is administered as an intravenous infusion over 24 hours with a three-week interval between cycles, the recommended dose is 1.5 mg/m^2 body surface area
  - [for this indication] meets SMC orphan and end of life criteria and was accepted for use in NHS Scotland following the output from the PACE process, and application of the appropriate SMC modifiers
- efficacy data are based mainly on liposarcoma and leiomyosarcoma patients. In practice use will mainly be in this patient group, however, there are certain translocation positive sarcomas that may benefit, e.g., mesenchymal chondrosarcomas.
- in the trial, patients had an ECOG performance score of 0 or 1
- the patent for trabectedin expires in September 2022
- patient numbers are expected to be very small
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of trabectedin

The Group accepted the restricted local need for trabectedin for the treatment of adults with advanced soft tissue sarcoma as outlined in SMC 2283.

SMC 2283 - Trabectedin 0.25mg, 1mg powder for concentrate for solution for infusion (Yondelis®) is routinely available in line with national guidance (SMC 2283).
Indication under review: for the treatment of adults with advanced soft tissue sarcoma, after failure of anthracyclines and ifosfamide, or who are unsuited to receive these agents.
Efficacy data are based mainly on liposarcoma and leiomyosarcoma patients. Trabectedin, compared with an alkylating chemotherapy, increased progression-free survival but not overall survival in patients with advanced liposarcoma or

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leiomyosarcoma who had previously been treated with an anthracycline-based chemotherapy.
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 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. Trabectedin must be administered under the supervision of a physician experienced in the use of chemotherapy. Its use should be confined to qualified oncologists or other health professionals specialised in the administration of cytotoxic agents. **FTEAM**

8.4. FG1SMC 2357 - OFATUMUMAB (MULTIPLE SCLEROSIS)

Ms Galvin declared a non-personal, non-specific interest in Novartis Pharmaceuticals UK Ltd, and took part in decision-making.

The Group considered the request for ofatumumab subcutaneous injection for the treatment of adults with relapsing-remitting multiple sclerosis (RRMS).

The Group noted that:

- ofatumumab:
  - is given at weeks 0, 1 and 2, followed by monthly dosing starting at week 4
  - is intended for self-administration by subcutaneous injection, and the service plans to supply via homecare
  - is likely to displace some of the existing second-line disease modifying therapies, e.g., natalizumab, ocrelizumab and fingolimod. Occasionally it may be used in preference to a first-line agent if the onset of MS is aggressive.
  - treatment will continue unless there are intolerable side effects, evidence of active disease by relapses or new lesions on MRI, or if patients develop progressive disease and/or an Expanded Disability Status Scale (EDSS) greater than 6.5
  - will free up MS nurse time and clinic space where it is used instead of disease modifying therapies given by infusion
- patient numbers are expected to be small but potentially cumulative where treatment is long-term
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of ofatumumab

The Group accepted the restricted local need for ofatumumab subcutaneous injection for the treatment of adults with RRMS as outlined in SMC 2357.

SMC 2357 - Ofatumumab 20mg/0.4mL solution for injection in pre-filled pen (Kesimpta®) ▼ is routinely available in line with national guidance (SMC 2357).
Indication under review: for the treatment of relapsing-remitting multiple sclerosis (RRMS) in adults with active disease defined by clinical or imaging features.
Two phase III studies demonstrated superiority of ofatumumab in reducing annualised relapse rate when compared with another disease-modifying treatment (DMT) in adult patients with relapsing forms of multiple sclerosis (RMS).
This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) 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 by a physician experienced in the management of neurological conditions. **FTEAM**

8.5. FGA 440/21 – NATALIZUMAB SUBCUTANEOUS INJECTION (MULTIPLE SCLEROSIS)

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

The Group considered the request for natalizumab as a subcutaneous injection for the treatment of adults with relapsing-remitting multiple sclerosis (RRMS).

The Group noted that:

- the subcutaneous formulation of natalizumab is considered outwith remit for the SMC
- natalizumab as the intravenous preparation has been assessed by SMC and is included on the formulary for patients with rapidly evolving severe RRMS defined by two or more disabling relapses in one year and with one or more gadolinium-enhancing lesions on brain magnetic resonance imaging (MRI) or a significant increase in T2 lesion load compared with a previous MRI (SMC 329/06)
- the two formulations have comparable pharmacokinetic/pharmacodynamic, efficacy and safety profiles, shown in two studies DELIVER and REFINE
- administration of the subcutaneous injection is to be performed by a healthcare professional and home treatment is not recommended
- natalizumab subcutaneous is given as a 300mg injection every 4 weeks. As each pre-filled syringe contains 150mg natalizumab two pre-filled syringes need to be administered to the patient.
- the cost of the subcutaneous and intravenous preparations are identical
- the availability of the subcutaneous preparation is expected to result in benefits for patients and staff by reducing preparation, administration, observation and chair time and no need for cannulation
- natalizumab biosimilars of the intravenous preparation are planned for launch in 2023

The Group accepted the restricted local need for natalizumab subcutaneous injection for the treatment of adults with rapidly evolving severe RRMS in line with SMC/HIS advice for natalizumab concentrate for solution for infusion.

FGA 440/21 - Natalizumab 150mg solution for injection in pre-filled syringe (Tysabri®) is routinely available in line with local guidance.
Indication under review: as single disease modifying therapy in adults with highly active relapsing remitting multiple sclerosis (RRMS) only in adults with rapidly evolving severe RRMS defined by two or more disabling relapses in one year, and with 1 or more Gadolinium enhancing lesions on brain Magnetic Resonance Imaging (MRI) or a significant increase in T2 lesion load as compared to a previous recent MRI.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Therapy is to be initiated and continuously supervised by specialised physicians experienced in the diagnosis and treatment of neurological conditions, with timely access to MRI. Home treatment is not recommended. Administration is to be performed by a healthcare professional and patients must be monitored for early signs and symptoms of Progressive Multifocal Leukoencephalopathy (PML). **FTEAM**

8.6. FG1 435/21 – MOVIPREP® (MECHANICAL BOWEL PREPARATION)

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

The Group considered the updated request to include MoviPrep®, a macrogol-based bowel cleansing preparation, on the formulary as an option for bowel cleansing prior to elective endoscopic colonoscopies.

The Group noted that:

- there are two bowel cleansing preparations available on the formulary for endoscopy procedures, Picolax® (picosulfate-based) and Klean-Prep® (macrogol-based), and Picolax® is the preferred agent
- MoviPrep® is a macrogol-based preparation, requested as an alternative to Picolax® or

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Klean-Prep® for patients who have had a failed colonoscopy, or for frail, elderly patients during the COVID pandemic
- MoviPrep® has the potential to be better tolerated than Picolax® and Klean-Prep®, less dehydrating than Picolax® and better compliance than Klean-Prep®, these advantages may result in fewer incomplete bowel clearances
- the request limited supply to the acute service, and that the possibility of pre-labelled supply was also being explored, however a recent email requested that supply via Primary Care was considered
- the change from Picolax® to a macrogol-based product will increase prescribing costs, but MoviPrep® costs less than Klean-Prep®

Members discussed the potential for supply via Primary Care in the context of the National Patient Safety Agency (NPSA) Rapid Response Report [NPSA/2009/RRR012].

The Group accepted the restricted local need for MoviPrep® as an additional bowel cleansing agent on the formulary, however mindful of the NPSA alert, the Group supported supply via the managed service as included in the submission.

Klean-Prep® will remain on formulary meantime but may be removed from the formulary in the future.

MoviPrep® powder for oral solution® is routinely available in line with local guidance.
Indication under review: in adults for bowel cleansing prior to any clinical procedures requiring a clean bowel, e.g., bowel endoscopy or radiology.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. **FTEAM**

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - SEPTEMBER 2021

The Group noted the SMC provisional advice issued September 2021.

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.

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - SEPTEMBER 2021

The Group noted the SMC advice published September 2021.

Following publication of the negative SMC recommendations, for amikacin liposomal nebuliser dispersion (Arikayce®) SMC 2369 and mercaptamine (Procysbi®) SMC 2374, these medicines will not be included on the Grampian Joint Formulary for the indications in question. **FTEAM**

The following SMC accepted medicines have not been processed within a 60-day timescale:
- SMC 2370 - selpercatinib (Retsevmo®) ▼ (submission expected)
- SMC 2365 - filgotinib (Jyseleca®) ▼ (submission received)
- SMC 2375 - pembrolizumab (Keytruda®) (submission received)

Local advice for these medicines and indications will be included in the September 2021 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'. **FTEAM**

ITEM SUBJECT ACTION

11. GENERAL INFORMATION FROM SCOTTISH MEDICINES CONSORTIUM

EXTENSION OF THE INTERIM ACCEPTANCE DECISION OPTION

From September 2021, the interim acceptance decision option has been extended to include medicines with a positive Medicines and Healthcare products Regulatory Agency (MHRA) Early Access to Medicines Scheme (EAMS) scientific opinion and/or included in the Innovative Licensing and Access Pathway (ILAP). This may support earlier patient access, where a medicine is plausibly cost-effective and data to be generated in the near future is expected to resolve clinical uncertainty. Further information is available on the SMC website; https://www.scottishmedicines.org.uk/about-us/latest-updates/extension-of-the-interim-acceptance-decision-option/.

12. DOCUMENTS FOR INFORMATION

The Group noted item 12.1 (Drug Safety Update August 2021).

13. AOCB

None.

DATE OF NEXT MEETING

Tuesday 19 October 2021 starting at 14.30 via Microsoft Teams.

CHAIRMAN'S SIGNATURE **DATE 19 OCTOBER 2021**