NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 20 July 2021 at 14:30 via Microsoft Teams

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

IN ATTENDANCE

Dr Jane Dymott, Consultant Diabetes, Endocrinology and General Medicine (for items 3 and 8.1)
Dr Andrew Hannah, Consultant Cardiologist (for items 3 and 8.1)
Dr Joshua Newmark, Specialty Trainee Registrar, Chemical Pathology (observer)

Note some items were taken outwith agenda order.

ITEM	SUBJECT	ACTION
	The Chairman welcomed members, opened the meeting and noted that a quorum was present. He confirmed that Dr Dymott and Dr Hannah would be joining the meeting for the discussion about sodium-glucose co-transporter-2 (SGLT2) inhibitor choices. The Chairman welcomed Dr Joshua Newmark to the meeting. Dr Newmark 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 15 JUNE 2021** The Group accepted the draft note of the June meeting subject to minor typographical changes. The corrected final approved minute will be in the public domain within 21 days of approval.	**FD**
	Items 3 and 8.1 were taken together.	
3.	**DISCUSSION RE SGLT2 INHIBITOR CHOICE(S)** The Group noted that: • dapagliflozin: ▪ is the first SGLT2 inhibitor licensed for the treatment of symptomatic chronic heart failure with reduced ejection fraction ▪ evidence comes from the DAPA-HF trial, and the Cardiology Service plans to use the same starting/inclusion criteria as DAPA-HF ▪ will be added to optimised heart failure treatments, and represents a new cost ▪ is also licensed and approved for use in NHS Scotland for Type 1 and Type 2 diabetes mellitus but is not currently included on the formulary for these indications • patients with Type 1 diabetes mellitus were excluded from the DAPA-HF trial due to the risk of diabetic ketoacidosis • the recommended dose [for chronic heart failure] is 10mg once a day, or 5mg once a day for those with severe hepatic impairment	

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- the flat pricing structure of the tablets means that people should be given a single 10mg tablet not two 5mg tablets

Dr Dymott and Dr Hannah confirmed that:

- from a diabetes perspective:
  - in Type 2 diabetes mellitus SGLT2 inhibitors are currently used second-line after metformin, and would be used as a preferred option for people with established cardiovascular disease or severely elevated albumin-to-creatinine ratios
  - the diabetic service tends to position classes of medicines rather than individual medicines, so the current choice is empagliflozin because it was the first SGLT2 inhibitor with cardiovascular outcome data, and canagliflozin because it has a wider licence for renal impairment and differed in its evidence for use in people with micro-albuminuria
  - the diabetic service is not keen on switching agents, and formulary choices need to meet the needs of patients (renal function etc.)
- from a heart failure perspective:
  - dapagliflozin looks like a valuable drug with a different mechanism of action to other agents used for heart failure, and with benefits to renal function (reduce progression of renal failure)
  - dapagliflozin will be widely applicable with a lot of people suitable for treatment
  - the Cardiology Service does not have major concerns about the negative aspects of dapagliflozins use
  - the benefits of dapagliflozin look to be additive to standard agents, including sacubitril valsartan, with improved mortality and reduced hospitalisations for heart failure
  - National Institute for Health and Care Excellence (NICE) states that treatment with dapagliflozin is initiated only on the advice of a heart failure specialist, and this position is supported locally
  - cardiologists and other physicians will need to increase their familiarity with SGLT2 inhibitors, and liaise with the diabetic service for particular people with diabetes where extra care may be required

Members queried how the situation would be managed where multiple specialists are looking after a patient and care overlaps with the differing specialists using similar medications, e.g., person with diabetes on empagliflozin seen in cardiology for heart failure.

Dr Dymott confirmed that the diabetic service has significant experience with SGLT2 inhibitors in the management of Type 2 diabetes and can support cardiology and primary care. In scenarios of co-morbidity cardiology could liaise with the person's usual diabetes team.
The specialist diabetes team will share SGLT2 inhibitor patient information leaflets with Cardiology.

Members noted the need for a degree of caution in use as colleagues in Primary Care do not have experience using SGLT2 inhibitors for non-diabetic patients, and rare/unexpected adverse drug reactions may be identified when medicines are used in an increased numbers of patients.

The Chairman thanked Dr Dymott and Dr Hannah for attending the meeting, and the consultants left the meeting before decision-making.

8.1 FG1SMC 2322 - Dapagliflozin (chronic heart failure with reduced ejection fraction)

Mr Paterson declared a personal, non-specific interest in AstraZeneca UK Limited and

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took part in decision-making.
The Group discussed formulary inclusion of dapagliflozin for the treatment of symptomatic chronic heart failure with reduced ejection fraction and Type 2 diabetes mellitus.

The Group agreed that:

- dapagliflozin:
  - would be a third SGLT2 inhibitor on the formulary, but the evidence base for SGLT2 inhibitors is changing with additional licences expected next year
  - would be a useful addition to formulary for both heart failure and Type 2 diabetes mellitus
- colleagues in Primary Care do not currently have experience of the use of dapagliflozin in heart failure, and for this indication, dapagliflozin should only be initiated on the advice of a heart failure specialist
- SGLT2 inhibitors are valuable agents for people with Type 2 diabetes mellitus and/or chronic heart failure

Mindful of the changing evidence base, that switching agents can be confusing for patients and causes significant workload issues for Primary Care colleagues, the Group supported including dapagliflozin as a third SGLT2 inhibitor on the formulary.

The Group accepted the restricted local need for dapagliflozin for the treatment of symptomatic chronic heart failure with reduced ejection fraction as outlined in SMC 2322, and as an additional SGLT2 inhibitor for the management of people with type 2 diabetes mellitus.

SMC 2322 - Dapagliflozin 5mg, 10mg film-coated tablets (Forxiga®) is routinely available in line with national guidance (SMC 2322).
Indication under review: in adults for the treatment of symptomatic chronic heart failure with reduced ejection fraction.
Restriction: start treatment on the advice of a heart failure specialist/cardiologist.
In a randomized, double-blind, phase III study, dapagliflozin demonstrated a significant reduction in the composite outcome of hospitalization for heart failure, urgent heart failure visit and cardiovascular death compared with placebo in patients with heart failure with reduced ejection fraction receiving current standard of care.
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. **FTEAM**

Dapagliflozin 5mg, 10mg film-coated tablets (Forxiga®) is routinely available in line with national guidance.
Indication under review: in adults with type 2 diabetes mellitus to improve glycaemic control as add-on combination therapy in combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control.
Restriction: in line with SMC/HIS advice for dapagliflozin for the treatment of type 2 diabetes mellitus.
It was classified 1b - available for restricted use under specialist supervision and 8d – treatment may be initiated in the community on the recommendation of a consultant/specialist. [Specialist to include GP/non-medical prescriber with a specialist interest in diabetes]. **FTEAM**

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.

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4.2. PAEDIATRIC LICENCE EXTENSIONS (UPDATE)

Ms Doney reported that work on the SMC list of paediatric licence extension is ongoing. Initially the plan was to complete the reviews by June 2021, however several issues were identified that have delayed completion of the initial SMC lists.
The Formulary Team is liaising with the SMC and colleagues in other Health Boards to improve the information that is issued by the SMC.

February 2021, there were 35 medicines/indications noted as receiving a paediatric licence extension since January 2020. Between March and June, the Group published 24 decisions for medicines with paediatric extensions, including new indications identified during the reviews.

The remaining medicines, and any new paediatric extensions (since February 2021), will be scheduled into the Formulary Team's workload.

This item was closed on the action log noting as deadline missed. **FD**

4.3. PHARMACY FIRST LIST AND PROCESS FEEDBACK (UPDATE)

The Formulary Group's comments on the approved list and process were discussed and ratified at the Grampian Area Drug and Therapeutics Committee (GADTC) meeting on 30 June.
The 'Pharmacy First' review process was supported subject to a couple of changes.

Additionally, the GADTC agreed that the Formulary Group was the appropriate forum to provide the local perspective for future reviews of the Pharmacy First Approved List, recognising that this is a new workload for the Formulary Team and Formulary Group.

Ms Doney confirmed that the Group's recommendations were submitted on the 30 June deadline.

5. FORMULARY GROUP DECISIONS JUNE 2021 - PUBLISHED 28/06/2021

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

6. NETFORMULARY/FORMULARY REVIEW

6.1. SECUKINUMAB 300MG PRE-FILLED PENS (NEW STRENGTH OF FORMULARY MEDICINE)

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

The Group considered the SBAR regarding the introduction of a new higher strength (300mg) secukinumab pre-filled pen.

The Group noted that:
- secukinumab
  - as the 150mg pre-filled pen and syringe is included on the formulary to treat psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis and plaque psoriasis
  - dosing varies by indication, and currently only non-radiographic axial spondyloarthritis does not include a 300mg dose
- currently patients receiving a 300mg dose take two 150mg subcutaneous injections
- the SMC advice for secukinumab takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of secukinumab 150mg, and the PAS has been updated to include the 300mg pre-filled pen

The Group agreed that access to the new higher strength preparation would be advantageous for patients requiring a 300mg dose. However, patients switching to the 300mg pre-filled pens should be fully counselled and aware that they only need to take

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one injection per dose.

The Group accepted the restricted local need for the higher strength 300mg secukinumab pre-filled pen, in line with current SMC/HIS acceptance for the 150mg pre-filled pen and syringe.

SBAR - Secukinumab 300mg pre-filled pen is routinely available in line with local guidance.
Indication under review: as licensed for adults with psoriatic arthritis, ankylosing spondylitis and plaque psoriasis.
Restriction: in line with SMC/HIS advice for secukinumab 150mg pre-filled pen and syringe.
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. Secukinumab is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of conditions for which secukinumab is indicated. **FTEAM**

6.2. 93-DAY REPORT (APRIL 2021 TO JUNE 2021)

Ms Doney confirmed that due to staffing issues the report was not available for the meeting, however, the Team is currently working within deadlines.

7. OTHER BUSINESS

7.1. CHLORAMPHENICOL EYE DROPS (UPDATE)

The Chairman reported that, following review [of the available toxicological data and a calculation of daily exposure to boron from a typical dosing regimen], the Medicines and Healthcare products Regulatory Agency (MHRA) has concluded that the balance between the benefits and risks of chloramphenicol eye drops containing borax or boric acid remains positive for children aged 0 to 2 years. Chloramphenicol eye drops can be safely administered to children aged 0 to 2 years where antibiotic eye drop treatment is indicated.

Ms Doney confirmed the formulary entry was updated 08/07/2021, removing the EMA warning and adding a link to the DSU article.
Additionally, the action to highlight other formulary boron-containing eye drops used in children aged 0 to 2 years was halted, and the action log entry closed.

8. NEW PRODUCT REQUESTS

8.2. FG1SMC 2317 - DUPILUMAB SOLUTION FOR INJECTION (SEVERE ASTHMA)

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

The Group reviewed the request for dupilumab as an add-on maintenance treatment for severe refractory asthma with type 2 inflammation.

The Group noted that:
- dupilumab:
  - blocks receptors for interleukin (IL)-4 and IL-13
  - is already included on the formulary for other indications
  - is given as a subcutaneous injection every two weeks, and the majority of patients learn to self-inject
  - is licensed for adults and adolescents aged 12 years and older. However, the paediatric service currently has no plans to prescribe dupilumab.
- the SMC advice takes account of the benefits of a PAS that improves the cost-

effectiveness of dupilumab
- the adult service plans to use dupilumab after either immunoglobulin E (IgE) or IL-5
- none of the patients in the dupilumab asthma studies had previously received a biological therapy, however the submitting company requested that SMC considered dupilumab for people who had previously received biologic treatment with anti-IgE or anti-IL-5 therapies

The Group accepted the restricted local need for dupilumab for severe refractory asthma with type 2 inflammation, as outlined in SMC 2317.

SMC 2317 - Dupilumab 200mg, 300mg solution for injection in pre-filled syringe and pen (Dupixent®) is routinely available in line with national guidance (SMC 2317). Indication under review: in adults and adolescents 12 years and older as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised fraction of exhaled nitric oxide (FeNO), who are inadequately controlled with high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment.
Restriction: for the treatment of patients with blood eosinophils ≥150cells/microlitre and FeNO ≥25 parts per billion, and ≥4 exacerbations in the preceding year, who have previously received biologic treatment with anti-IgE or anti-IL-5 therapies.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be initiated by healthcare professionals experienced in the diagnosis and treatment of conditions for which dupilumab is indicated. FTEAM

8.3. FG1SMC 2194 - PENTOSAN POLYSULFATE SODIUM (BLADDER PAIN SYNDROME)

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

The Group reviewed the request for pentosan polysulfate sodium for the treatment of bladder pain syndrome characterised by either glomerulations or Hunner's lesions in adults with moderate to severe pain, urgency and frequency of micturition.

The Group noted that:
- pentosan polysulfate sodium:
  - is the only medicine specifically licensed for bladder pain syndrome
  - is currently being prescribed within NHS Grampian, as a second-line option (on a named patient basis), along with intravesical instillations in patients who fail or who get a partial response to first-line treatments
  - [for this indication] meets SMC orphan equivalent criteria, and was accepted for use in NHS Scotland following a full submission considered under the orphan equivalent medicine process, the output from the PACE process, and application of the appropriate SMC modifiers
- NICE has advised that pentosan polysulfate sodium should not be offered in combination with bladder instillations, which differs from the SMC advice. Locally, pentosan polysulfate is given as a second-line alternative to bladder instillations, some patients may require both.
- the evidence for pentosan polysulfate sodium comes from trials ranging from 3 to 6 months which is relatively short for treatment of a chronic condition, and the trials were compared to placebo not a relevant comparator
- at present the majority of supplies come from hospital pharmacy, but if accepted to formulary, the service hopes to supply via primary care for people that respond to treatment, i.e., after six months treatment supplied from the managed service
- the majority of 'responders' will continue treatment regularly, however, a small minority of patients may receive treatment intermittently
- the Summary of Product Characteristics (SmPC) is not available on the electronic

medicines compendium, if accepted for use the SmPC will be linked to the formulary entry
- the service confirmed that for patients responding to treatment, ophthalmologic examination will be carried out after six months treatment [for early detection of pigmentary maculopathy] and if there are no pathologic findings, regularly after 5 years. In cases of relevant ophthalmologic findings, a yearly examination should be conducted.

The Group discussed the need for ongoing review of efficacy and safety, and questioned how the need for ophthalmological review would be triggered to ensure patients were not missed or lost to follow-up.

The Group acknowledged that:
- pentosan polysulfate sodium:
  - is an expensive medicine with limited efficacy data
  - does not require specific drug monitoring but needs regular review of benefits and safety, particularly ophthalmological review for irreversible pigmentary maculopathy
  - has the potential to be used long-term for 'responders' so patient number may increase with time
  - would be prescribed on the advice of a specialist, and Primary Care clinicians are not familiar with this medicine

The Group was unclear if urology waiting lists would allow for an ongoing review of efficacy for a cohort of 'responders', how ophthalmological review would be triggered and if the ophthalmological review would be done via the managed service or could be arranged via the Eye Health Network.

To aid safe prescribing for 'responders', the Group requested supporting prescribing information that also clarified the arrangements for the ongoing review of efficacy and safety.

The Group accepted the restricted local need for pentosan polysulfate sodium for the treatment of adults with bladder pain syndrome as outlined in SMC 2194. Approval is subject to provision of information for prescribers in Primary Care, and clarity about the arrangements for review of efficacy and safety, particularly the ophthalmological review.

SMC 2194 - Pentosan polysulfate sodium 100mg hard capsules (Elmiron®) is routinely available in line with national guidance (SMC 2194).
Indication under review: for the treatment of bladder pain syndrome characterised by either glomerulations or Hunner's lesions in adults with moderate to severe pain, urgency and frequency of micturition.
In patients with bladder pain syndrome and glomerulations or Hunner's lesions, pentosan polysulfate sodium was associated with significantly more patients achieving at least moderate improvement in overall symptoms of bladder pain syndrome compared with placebo.
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. FTEAM

8.4. FG1SMC 2303 - ISATUXIMAB CONCENTRATE FOR SOLUTION FOR INFUSION (RELAPSED AND REFRACTORY MULTIPLE MYELOMA)

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

The Group considered the request for isatuximab in combination with pomalidomide and dexamethasone, as a fourth-line treatment option for adults with relapsed and refractory multiple myeloma (RRMM).

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The Group noted that:

- isatuximab:
  - [for this indication] is used in combination with pomalidomide and dexamethasone, and will mean an intravenous preparation is added to a previous oral treatment regimen
  - has also recently been licensed in combination with carfilzomib and dexamethasone for the treatment of adults with MM who have received at least one prior therapy
  - [for this indication] meets SMC end of life and orphan equivalent criteria, and was accepted for restricted 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 isatuximab
- in the ICARIA study only one patient had previously received daratumumab which is unlikely to be the case in practice
- the requestor has stated that pomalidomide and dexamethasone, a current third-line treatment option, will be moved to fourth-line in combination with isatuximab, meaning there is no clear third-line regimen, and third-line treatment will be tailored to individual patients
- patient numbers are expected to be small

The Group accepted the restricted local need for isatuximab [in combination with pomalidomide and dexamethasone] for the treatment of RRMM as outlined in SMC 2303.

SMC 2303 - Isatuximab 20mg/mL concentrate for solution for infusion (Sarclisa®) ▼ is routinely available in line with national guidance (SMC 2303).
Indication under review: as a fourth-line therapy in combination with pomalidomide and dexamethasone, for the treatment of adults with relapsed and refractory multiple myeloma (RRMM) in patients who have received lenalidomide and a proteasome inhibitor (PI) and have demonstrated disease progression on the last therapy.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Isatuximab should be administered by a healthcare professional, in an environment where resuscitation facilities are available. FTEAM

8.5. FG1SMC 2318 - CHLORMETHINE HYDROCHLORIDE GEL (MYCOSIS FUNGOIDES-TYPE CUTANEOUS T-CELL LYMPHOMA)

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

The Group considered the request for chlormethine hydrochloride gel for the topical treatment of mycosis fungoides-type cutaneous T-cell lymphoma (MF type CTCL) in adults.

The Group noted that:

- chlormethine gel:
  - is a topical cytotoxic agent, so when the expiry date is reached or the contents used up, the tube, any remaining gel, the carton, the plastic bag and any nitrile gloves used for application should be disposed of according to specific local procedures.
    The service plans to supply patients with purple-topped cin bins which can be returned to Dermatology.
  - will not replace any current treatments but will provide an additional skin directed therapy
  - [for this indication] meets SMC orphan criteria, and was accepted for use in NHS Scotland following the output from the PACE process and application of the

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appropriate SMC modifiers
  - requires to be stored and transported frozen (-15°C to -25°C) before dispensing, as once defrosted and stored cooled in a refrigerator (+2°C to +8°C) it has a shelf-life of 60 days
- in Study 201 the median duration of treatment was 51.7 weeks, however the service has stated that, if effective, treatment courses are likely to be repeated for new areas of disease
- the service would not generally use chlormethine gel on a significant body surface area, and expects patients will use a maximum of 2-4g per application, likely less in most cases
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of chlormethine gel, however the PAS is not currently available to Primary Care

The Group accepted the restricted local need for chlormethine gel for the topical treatment of MF type CTCL as outlined in SMC 2318.

SMC 2318 - Chlormethine hydrochloride 160microgram/g gel (Legada®) is routinely available in line with national guidance (SMC 2318).
Indication under review: for the topical treatment of mycosis fungoides-type cutaneous T-cell lymphoma (MF type CTCL) in adults.
In a single-blind, randomised, phase II study, chlormethine gel was non-inferior to a compounded chlormethine ointment based on ≥50% improvement in Composite Assessment of Index Lesion Severity (CAILS) score confirmed after 4 weeks.
It was classified 1b - available for restricted use under specialist supervision and 8b – recommended for hospital use only. Treatment should be initiated by an appropriately experienced physician. FTEAM

8.6. FG1SMC 2278 - VABOREM® (INFECTIONS)

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

The Group considered the request for Vaborem®, a combination product containing the two antibacterials meropenem and vaborbactam.

The Group noted:
- Vaborem®:
  - is given as an intravenous infusion over 3 hours every 8 hours for 5 to 14 days
  - contains 1500mg sodium per daily dose, equivalent to 75% of the World Health Organization recommended maximum daily intake
  - will not replace current treatment but will be used last line on the advice from a consultant in microbiology or infectious diseases
- the limitations of the clinical data
- the use of Vaborem® would be subject to antimicrobial prescribing policies and antimicrobial stewardship

The Group accepted the restricted local need for Vaborem® as outlined in SMC 2278 noting that prescribing is restricted to 'only on the advice of a Consultant/Specialist Microbiologist or infectious disease specialist'. Approval is subject to inclusion in the 'NHS Grampian staff guidance for optimising use of alert (restricted) antimicrobials'.

SMC 2278 - Vaborem® 1 gram/1 gram (meropenem/vaborbactam) powder for concentrate for solution for infusion is routinely available in line with national guidance (SMC 2278).
Indication under review: for the treatment of adults with confirmed carbapenem-resistant *Enterbacteriaceae* (CRE), which is involved in the production of *Klebsiella pneumoniae* carbapenemase (KPC) associated with complicated urinary tract

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infection (including acute pyelonephritis [AP]), complicated intra-abdominal infection, hospital acquired pneumonia (HAP (including ventilator associated pneumonia [VAP]) and bacteraemia that occurs in association with, or is suspected to be associated with any of the infections previously mentioned. Use should be on the advice of local microbiologists or specialists in infectious disease.
It was classified 1b - available for restricted use under specialist supervision and 8b – recommended for hospital use only. Consideration should be given to official guidance on the appropriate use of antibacterial agents.
Vaborem® should be used to treat infections due to aerobic Gram-negative organisms in adult patients with limited treatment options only after consultation with a physician with appropriate experience in the management of infectious diseases (see SmPC 4.4 and 5.1). **FTEAM**

8.7. SMC 2321 - TRIXEO® AEROSPHERE® 5MICROGRAMS/7.2MICROGRAMS/160MICROGRAMS PRESSURISED INHALATION, SUSPENSION

Item deferred.

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - JULY 2021

The Group noted the SMC provisional advice issued July 2021.

If the SMC non-submission statement is published next month, this medicine will not be included on the formulary for the indication in question.

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - JULY 2021

The Group noted the SMC advice published July 2021.

Following publication of the SMC not recommended statement, for tafamidis (Vyndaqel® ▼) (SMC 2354), and the non-submission statements, for fostemsavir (Rukobia® ▼) (SMC 2389), Recarbrio® ▼ (imipenem/cilastatin/relabactam) (SMC 2390) and delafloxacin (Quofenix® ▼) (SMC 2393), 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 2349 atezolizumab (Tecentriq®) (submission received)
- SMC 2357 ofatumumab (Kesimpta®) (submission received)
- SMC 2363 bempedoic acid (Nilemdo®) ▼ (submission received)
- SMC 2364 Phesgo® (pertuzumab/trastuzumab) ▼ (submission expected)

Local advice for these medicines and indications will be included in the July 2021 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

Ms Doney reported that the SMC Executive has recently agreed an update to the ultra-orphan validation process. From 1 September 2021, ultra-orphan validation decisions will expire after two years. Thereafter if a product has MHRA marketing authorisation, if there are eligible patients in NHS Scotland and if no submission is forthcoming, SMC will move to issue 'Not Recommended' advice.

12. DOCUMENTS FOR INFORMATION

The Group noted items 12.1, 12.2 (Drug Safety Update June and July 2021), 12.3, 12.4 (MEDwatch June and July 2021) and 12.5 (Antimicrobial Management Team Meeting 29 April 2021) were noted.

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13. AOCB

REGISTER OF INTEREST 2020

Ms Doney asked members to review and approve their entry for the 2020 conflicts of interests register. The Formulary Team plans to upload the register to the intranet at the end of the month. — ALL FTEAM

DATE OF NEXT MEETING

Tuesday 17 August 2021 starting at 14.30 via Microsoft Teams.

CHAIRMAN'S SIGNATURE **DATE 17 AUGUST 2021**