

NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 15 December 2020 at 14:30 via Microsoft Teams

PRESENT

Ms A Davie
Ms F Doney
Dr L Elliot
Dr J Fitton
Mrs L Harper
Professor J McLay (Chairman)
Dr M Metcalfe
Mrs L Montgomery
Mrs K Neave
Mr M Paterson
Mr C Rore
Mr R Sivewright

APOLOGIES

Ms M Galvin
Dr A Sun

APPROVED

IN ATTENDANCE

Dr Simon Sawhney, Consultant Nephrologist (for items 3 and 4.1)
Ms Caitlin Wilkinson, Formulary Team administrator

ITEM	SUBJECT	ACTION
	The Chairman 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 17 NOVEMBER 2020 The Group accepted the draft note of the meeting subject to minor typographical changes and rewording of section 4.1 <i>“Decisions taken during the interim governance arrangements”</i> . The corrected final approved minute will be in the public domain within 21 days of approval.	FD
3.	PRESENTATION The Chairman welcomed Dr Simon Sawhney, Consultant Nephrologist, to the meeting to discuss the request for sodium zirconium cyclosilicate. Dr Sawhney provided the Group with an overview of the licensing data for sodium zirconium cyclosilicate and the Renal Department’s position regarding the use of sodium zirconium cyclosilicate. Dr Sawhney reported that: <ul style="list-style-type: none">• sodium zirconium cyclosilicate is a potassium binder with two potential indications:<ul style="list-style-type: none">▪ acute use - in the emergency setting to bring down potassium abruptly in acute life-threatening hyperkalaemia▪ chronic use – to allow the introduction of renin-angiotensin-aldosterone system (RAAS) inhibitors where there is proven benefit, i.e. heart failure and proteinuric kidney disease. [RAAS inhibitors include angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers (ARBs) and aldosterone receptor antagonists. ACE-I RAS blockers].• on review of the local data, there is a divergence from the AstraZeneca estimate of patient numbers; locally treatment numbers would be much smaller• the Renal Service supports the Renal Association hyperkalaemia guidelines which suggests that:<ul style="list-style-type: none">▪ sodium zirconium cyclosilicate can be considered as an “option” in those with a serum potassium $\geq 6\text{mmol/L}$ who either have chronic kidney disease (not on dialysis)	

ITEM	SUBJECT	ACTION
	<ul style="list-style-type: none"> or heart failure needing RAAS inhibitor therapy ▪ sodium zirconium cyclosilicate should be stopped if a person is no longer taking a RAAS inhibitor therapy ▪ sodium zirconium cyclosilicate should only be started in Secondary Care, with shared blood monitoring with Primary Care ▪ potassium binders are an option for emergency management of acute life-threatening hyperkalaemia (≥ 6.5mmol/L), but haemodialysis is prioritised within their grades of evidence ▪ potassium binders may be considered to reduce the risk of hyperkalaemia during the interdialytic period [limited evidence] <ul style="list-style-type: none"> • sodium zirconium cyclosilicate has the potential for harm - hypokalaemia and oedema (which would always be a problem when loading with sodium) • the majority of hyperkalaemia is turned around rapidly with volume and cessation of medicines • the potential areas (number of people with a potential indication) where sodium zirconium cyclosilicate could be used are greater than where there is real benefit to the use of sodium zirconium cyclosilicate and there are no alternative treatment options • the Renal Department supports limited use of sodium zirconium cyclosilicate, and sees individual situations where there may be potential value: <ol style="list-style-type: none"> 1) individual basis – people with recurrent hyperkalaemia; particularly in a younger group of people with advanced heart failure that would benefit from an ACE inhibitor but cannot start it [small patient numbers]. In this scenario – sodium zirconium cyclosilicate would be initially prescribed by the specialist service with weekly monitoring over the first month before looking to share care with General Practice doing monthly bloods. 2) emergency bridging use where dialysis is unavailable, for unforeseen (loss of water supply) and predictable circumstances (bridging dialysis), in this scenario use is solely as in-patient or in the dialysis unit, and for a maximum of two to three days • [in renal patients] if there is a way of treating a person's hyperkalaemia with dialysis then they would receive dialysis to remove potassium (and other toxins). There are instances where dialysis is indicated but not possible, e.g. dialysis access stable for some time but access is lost (e.g. fistula that thromboses) and the person needs a dialysis line. In this situation, fitting a line is no longer straightforward and interventional radiology input is required. Dialysis access may be delayed and sodium zirconium cyclosilicate can be used to provide a bridge to access. 	

The Chairman thanked Dr Sawhney for attending the meeting and providing members with a clear and informative update on the potential use of sodium zirconium cyclosilicate. Dr Sawhney left the meeting before decision-making.

4. MATTERS ARISING

4.1. FG1SMC 2288 - SODIUM ZIRCONIUM CYCLOSILICATE (HYPERKALAEMIA)

Dr Fitton and Mr Paterson declared personal, non-specific interests in AstraZeneca UK Limited and took part in the discussion.

The Group considered the additional information provided to support the request for sodium zirconium cyclosilicate in the management of adult patients with hyperkalaemia. The Group noted:

- that emergency use is not included in the SMC advice, and the suggested use is akin to the NICE guidance
- sodium zirconium cyclosilicate:
 - has a high sodium load with known/expected adverse effects [oedema and hypokalaemia]
 - is an expensive drug with the potential for use to creep into other service areas

PROTECTIVE MARKING: NONE

ITEM	SUBJECT	ACTION
	<ul style="list-style-type: none">• there is limited evidence for long-term use, and the studies are not restricted to serum potassium levels of ≥ 6mmol/L• there is no evidence of improved outcomes for patients that were able to continue RAAS inhibitor therapies because they were co-prescribed sodium zirconium cyclosilicate• other non RAAS inhibitor therapies, with positive outcome data, are available for the management of heart failure• many clinicians would not support therapeutic escalation, where an additional medicine is used in a way that may disguise a potentially serious adverse drug event that requires investigation, e.g. sodium zirconium cyclosilicate for a rising potassium level caused by an ACE-inhibitor in a person with bilateral renal artery stenosis	

The Group recognised that sodium zirconium cyclosilicate has the potential to benefit a small group of patients, and could see the value of sodium zirconium cyclosilicate as an additional agent in the acute setting. In the chronic use setting, concerns remain around therapeutic escalation, the arrangements for long-term review and the risk of patients continuing treatment when RAAS inhibitor therapies were stopped.

The Group considered sodium zirconium cyclosilicate a relatively specialist medicine, with no clear guidance for weaning patients off treatment, or for the management of long-term treatment. At this time and without clear guidance, the Group was not minded to support moving prescribing to Primary Care.

The Group was minded to support the use of sodium zirconium cyclosilicate in limited circumstances however greater clarity is required on:

- the indication(s) requested for formulary inclusion (acute/intermittent/and possible chronic use)
- the potential patient numbers for the requested indications, and the proposed prescribing and monitoring arrangements (particularly for chronic use)
- the service area or areas that will prescribe sodium zirconium cyclosilicate - only by nephrology?

FTeam

4.2. ACTION LOG

The action log was noted.

No additional items were identified that should have been included on the agenda.

Ms Doney confirmed that updates for audits or reviews that were delayed due to COVID-19 would be chased in the next two to three months.

FTeam

4.3. PRIADEL[®] (DISCONTINUATION UPDATE)

The Chairman highlighted the Medicines and Healthcare products Regulatory Agency (MHRA) press release regarding the Competition and Markets Authority (CMA) investigation into the potential withdrawal of Priadel[®].

The CMA launched a competition law investigation into Essential Pharma because of suspicions that the firm may have abused its dominant position by proposing to withdraw the supply of the bipolar drug, Priadel[®] (lithium), to UK patients. If Priadel[®] was withdrawn, this would require patients to switch to alternative, more expensive treatments such as Camcolit[®], which is also owned by Essential Pharma.

Following the opening of the CMA's investigation, Essential Pharma paused the withdrawal of Priadel[®] and entered into price negotiations with the Department for Health and Social Care (DHSC). This has resulted in a recent agreement with the DHSC on a revised price for Priadel[®] that is still lower than alternative bipolar drugs.

Essential Pharma has now also offered formal commitments to the CMA to address competition concerns regarding its strategy in relation to Priadel[®]. These proposed

PROTECTIVE MARKING: NONE

ITEM	SUBJECT	ACTION
	<p>commitments would last for 5 years and include continuing to supply Priadel® on terms agreed with the DHSC. It would mean that the company could not threaten to withdraw Priadel® in order to increase the price without good reason.</p> <p>A final decision from the CMA is awaited. The investigation by the CMA is ongoing and no decision has been made as to whether the law has been broken. However, if the commitments are accepted by the CMA, they will become legally binding, which means Essential Pharma cannot choose to retract them.</p>	
	<p>4.4. TRIENTINE</p> <p>There were no declarations of interest recorded in relation to these products.</p> <p>Ms Doney confirmed that since June 2020 the Formulary Team has been monitoring the availability of licensed trientine dihydrochloride products. Two licensed products are now marketed in the UK, and confirmation of the formulary classification and supply route [for trientine] is required.</p> <p>Ms Doney reported that:</p> <ul style="list-style-type: none">• at the June 2020 Formulary Executive Group meeting trientine, as the tetrahydrochloride and dihydrochloride salts, was accepted to the formulary for the treatment of Wilson's disease in adults, adolescents and children ≥5 years intolerant to D-penicillamine therapy. A decision regarding formulary classification was delayed pending marketing of licensed trientine dihydrochloride capsules.• previously trientine dihydrochloride capsules were only available as unlicensed products, however licensed products are now marketed in the UK• the MHRA recommends that an unlicensed medicine should only be used when a patient has special requirements that cannot be met by the use of a licensed medicine• patient numbers are expected to be very small• previously prescriptions have been issued in Primary Care, with treatment initiated in Primary Care on the recommendation of a consultant/specialist• contract prices are available for trientine products, and the prices are available to Primary Care <p>The Group accepted the restricted local need for licensed trientine products for the management of Wilson's disease, noting that treatment may be initiated in the community on the recommendation of a consultant/specialist.</p> <p>Trientine dihydrochloride capsules is routinely available in line with local guidance. Indication under review: for the treatment of Wilson's disease in patients intolerant to D-Penicillamine therapy, in adults, adolescents and children aged 5 years or older. 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 should only be initiated by specialist physicians with experience in the management of Wilson's disease.</p>	
5.	<p>FORMULARY GROUP DECISIONS NOVEMBER 2020 – PUBLISHED 30 NOVEMBER 2020</p> <p>5.1. FORMULARY GROUP DECISIONS NOVEMBER 2020</p> <p>Members ratified the decisions of the November 2020 meeting as published.</p>	FTeam
6.	<p>NETFORMULARY/FORMULARY REVIEW</p> <p>6.1. SBAR - INTRAVAGINAL OESTROGEN PREPARATIONS</p> <p>There were no declarations of interest recorded in relation to these products.</p> <p>The Group noted that:</p> <ul style="list-style-type: none">• Ovestin® 1mg cream is supplied with a reusable applicator and remains a cost-effective	FTeam

PROTECTIVE MARKING: NONE

ITEM	SUBJECT	ACTION
	<p>first-choice intravaginal oestrogen product</p> <ul style="list-style-type: none">• two new estradiol 10microgram vaginal tablets are now marketed in the UK, and as these are generic medicines they are considered outwith remit for the SMC• the two generic 10microgram tablets are supplied with a single reusable applicator, whereas the reference product, Vagifem®, is supplied with 24 individually loaded applicators (use and dispose)• the newer products cost less than Vagifem® and address environmental concerns regarding single-use plastic, and some patients may choose a product with a reusable applicator for this reason• although noted as a second-line choice on the formulary, there is a potential that Vagifem® is prescribed as a first-line option• the availability of the new 10microgram tablets, and first-line use of Ovestin® 1mg cream in appropriate women, may provide an opportunity for cost minimisation• another two products have come to market, Blisse® and Imvaggis® [50microgram/g gel and 30microgram pessary respectively], and in the absence of a formulary request both will be considered non-formulary. A change in formulary classification would be subject to advice from the specialist service.	

The Group accepted the restricted local need for estradiol 10microgram vaginal tablets with reusable applicators.

The Group agreed that there is an educational element to the presentation and use of the intravaginal products, and that information regarding the differences between the products should be made available to prescribers. Ms Davie and Ms Doney will discuss and take forward this action outwith the meeting.

FD/AD

7. OTHER BUSINESS

7.1. NEW GRAMPIAN PUBLIC-FACING WEBSITE

Ms Doney reported that the new public facing NHS Grampian website went live on Thursday 3 December 2020. The new website includes a section for Formulary Group decisions, minutes etc.

8. NEW PRODUCT REQUESTS

8.1. FG1SMC 2282 - POLATUZUMAB VEDOTIN (LARGE B-CELL LYMPHOMA)

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

The Group considered the request for polatuzumab vedotin, in combination with bendamustine and rituximab, for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma who are not candidates for haematopoietic stem cell transplant.

The Group noted that:

- polatuzumab vedotin [used in combination with bendamustine and rituximab]:
 - [for this indication] was designated an 'orphan medicine' and received a 'conditional marketing authorisation' from the European Medicines Agency (EMA)
 - [August 2020] was accepted by the SMC executive for use in NHS Scotland on an interim basis subject to ongoing evaluation and future reassessment, following review of a full submission for an end of life and orphan medicine
 - would be used for patients who are not candidates for haematopoietic stem cell transplant
 - showed improved outcomes in terms of response and progression-free survival, and the median length of treatment in the clinical trial was five cycles [maximum six cycles]
- treatment will also be used as a bridging treatment to chimeric antigen receptor T-cell (CAR-T) therapy, and in this setting patients would only receive one or two cycles

PROTECTIVE MARKING: NONE

ITEM	SUBJECT	ACTION
	<ul style="list-style-type: none">• patient numbers in both settings are expected to be small• the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of polatuzumab• currently only a 140mg vial is available, however next year a 30mg vial will be marketed and the PAS discount rate will change when the 30mg vial becomes available• introduction of the 30mg vial will have significant additional implications for the Aseptic Unit	

Ms Doney confirmed that, at present, it is not known if the 140mg vial will be withdrawn when the 30mg vial becomes available.

The Group accepted the restricted local need for polatuzumab vedotin, used in combination with bendamustine and rituximab, for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma who are not candidates for haematopoietic stem cell transplant, as outlined in SMC 2282.

SMC 2282 - Polatuzumab vedotin 30mg, 140mg powder for concentrate for solution for infusion (Polivy®) ▼ is routinely available in line with national guidance, on an interim basis subject to ongoing evaluation and future reassessment (SMC 2282).

Indication under review: in combination with bendamustine and rituximab for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma who are not candidates for haematopoietic stem cell transplant.

In a phase Ib/II study polatuzumab vedotin in combination with bendamustine and rituximab significantly increased complete response rate compared to bendamustine and rituximab alone.

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.

Polatuzumab vedotin must only be administered under the supervision of a healthcare professional experienced in the diagnosis and treatment of cancer patients.

FTeam

8.2. FG1SMC 2224 - RUCAPARIB (OVARIAN, FALLOPIAN TUBE OR PRIMARY PERITONEAL CANCER)

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

The Group considered the request for rucaparib as monotherapy for the maintenance treatment of adult patients, who do not have a BRCA (BREast CAncer gene) mutation, with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy.

The Group noted:

- rucaparib:
 - is an inhibitor of poly (ADP-ribose) polymerase (PARP) enzymes, PARP-1, 2 and 3
 - is the third oral PARP inhibitor to be licensed for the maintenance treatment of relapsed, platinum-sensitive advanced ovarian, fallopian tube, or primary peritoneal cancer
 - was granted a 'conditional marketing authorisation' from the EMA and licensing is based on small patient numbers
 - [March 2020] was accepted for restricted use by the SMC, following a full submission assessed under the end of life and orphan medicine process
 - [for this indication] was accepted for use in NHS Scotland following the output from the PACE process and application of the appropriate SMC modifiers

PROTECTIVE MARKING: NONE

ITEM	SUBJECT	ACTION
	<ul style="list-style-type: none">the SMC restricted use to patients who do not have a BRCA mutation, and rucaparib would be an alternative treatment to niraparib [which is also available for patients who do not have BRCA mutation]the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of rucaparibpatient numbers are expected to be smallwhen used instead of niraparib cost offset will be availableniraparib is currently only accepted by SMC for serous epithelial cancer, whereas rucaparib is accepted for serous and endometrioid cancer, so would be available for a new group of patients - BRCA negative patients with endometrioid cancer	

The Group accepted the restricted local need for rucaparib as monotherapy for the maintenance treatment of adult patients, who do not have a BRCA mutation, with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy, as outlined in SMC 2224.

SMC 2224 – Rucaparib 200mg, 250mg, 300mg film-coated tablets (Rubraca®) ▼ is routinely available in line with national guidance (SMC 2224).

Indication under review: as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy.

Restriction: to patients who do not have a BRCA mutation.

Rucaparib significantly improved progression free survival compared with placebo in a phase III study in patients with platinum-sensitive serous or endometrioid ovarian, primary peritoneal or fallopian tube carcinoma who had received at least two previous platinum-based chemotherapy regimens.

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 views from a Patient and Clinician Engagement (PACE) meeting.

It was classified 1b - available for restricted use under specialist supervision and 8b – recommended for hospital use only.

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

FTeam

Items 8.3 and 8.4 were taken together.

8.3. FG1SMC 2262 - CANNABIDIOL (DRAVET SYNDROME)

8.4. FG1SMC 2263 - CANNABIDIOL (LENNOX-GASTAUT SYNDROME)

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

The Group considered the two formulary requests for cannabidiol oral solution, as licensed, for use as adjunctive therapy of seizures associated with Dravet syndrome or Lennox-Gastaut syndrome (LGS), in conjunction with clobazam, for patients 2 years of age and older.

The Group noted:

- Dravet syndrome:
 - is a severe lifelong condition characterised by seizures beginning in the first year of life. Patients generally have significant developmental delay apparent from the second year of life onwards with dependency needed in adulthood.
 - currently the only treatment specifically licensed for the treatment of Dravet syndrome is stiripentol [SMC 524/08] but sodium valproate, clobazam and

PROTECTIVE MARKING: NONE

ITEM	SUBJECT	ACTION
	<p>topiramate (licensed for use in epilepsy) are widely used in Dravet syndrome</p> <ul style="list-style-type: none">▪ locally, treatment is in line with NICE guidance• LGS:<ul style="list-style-type: none">▪ is a severe form of epilepsy that starts in childhood between 2 and 5 years of age. Patients have different types of seizures and most children experience some degree of learning disability and developmental delay, along with behavioural problems such as hyperactivity and aggression.▪ current licensed treatments for LGS include lamotrigine, topiramate and rufinamide, and sodium valproate and clobazam (licensed for use in epilepsy) are also widely used• cannabidiol [oral solution]:<ul style="list-style-type: none">▪ enhances the activity of clobazam [increases by 3-fold the clobazam active metabolite (N-desmethylclobazam) and increases by 1.5 fold the cannabidiol active metabolite (7-hydroxy-cannabidiol)]▪ [August 2020] was accepted for use in NHS Scotland following full submissions under the orphan process. Acceptance was subject to the output from the PACE process and application of the appropriate SMC modifiers.▪ is a Schedule 5 Controlled Drug [records of prescriptions need to be kept for 2 years]▪ is an adjunctive therapy so there is no cost offset available; this will be a new cost to the Health Board▪ is dosed on a mg/kg basis, and treatment may be added to current antiepileptic therapy• for Dravet syndrome the paediatric service follows NICE guidance for discontinuation criteria, and these criteria are discussed and agreed with carers prior to commencing treatment• the SMC detailed advice documents take account of the benefits of a PAS that improves the cost-effectiveness of cannabidiol oral solution• patient numbers, for both indications, are expected to be small and there is a potential for use in both paediatric and adult services• prescribing and monitoring will remain with the specialist services, with prescriptions issued on a hospital-based prescription [HBP]• adverse effects may limit treatment <p>The Group accepted the restricted local need for cannabidiol 100mg/mL oral solution for use as adjunctive therapy of seizures associated with Dravet syndrome or LGS, in conjunction with clobazam, for patients 2 years of age and older.</p> <p>SMC 2262 - Cannabidiol 100mg/mL oral solution (Epidyolex®) is routinely available in line with national guidance (SMC 2262). Indication under review: for use as adjunctive therapy of seizures associated with Dravet syndrome, in conjunction with clobazam, for patients 2 years of age and older. In two phase III, placebo-controlled studies cannabidiol reduced convulsive seizure frequency in the clobazam-treated subgroup of children (aged 2 to 18 years) with Dravet syndrome that was inadequately controlled by other anti-epileptic drugs. 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 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 physicians with experience in the treatment of epilepsy.</p>	

FTeam

PROTECTIVE MARKING: NONE

ITEM	SUBJECT	ACTION
	<p>SMC 2263 - Cannabidiol 100mg/mL oral solution (Epidyolex®) is routinely available in line with national guidance (SMC 2263).</p> <p>Indication under review: for use as adjunctive therapy of seizures associated with Lennox-Gastaut syndrome, in conjunction with clobazam, for patients 2 years of age and older.</p> <p>In two phase III, placebo-controlled studies cannabidiol reduced drop seizure frequency in the clobazam-treated subgroup of children and adults (aged 2 to 55 years) with Lennox-Gastaut syndrome that was inadequately controlled by other anti-epileptic drugs.</p> <p>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.</p> <p>This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.</p> <p>It was classified 1b - available for restricted use under specialist supervision and 8b – recommended for hospital use only.</p> <p>Treatment should be initiated and supervised by physicians with experience in the treatment of epilepsy.</p>	<p>FTeam</p>
9.	<p>SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - DECEMBER 2020</p> <p>The Group noted the SMC provisional advice issued December 2020.</p> <p>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.</p>	<p>FTeam</p>
10.	<p>SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS – DECEMBER 2020</p> <p>The Group noted the SMC advice published December 2020.</p> <p>Following publication of the negative SMC recommendation, for bempedoic acid ▼ SMC 2292, this medicine will not be included on the Grampian Joint Formulary for the indication in question.</p> <p>The following SMC accepted medicines have not been processed within a 60-day timescale:</p> <ul style="list-style-type: none">• SMC 2293 venetoclax (Venclyxto®) ▼ (submission expected)• SMC 2307 mexiletine (Namuscla®)• SMC 2296 avatrombopag (Doptelet®) ▼ (submission expected) <p>Local advice for these medicines and indications will be included in the December 2020 decisions as ‘Not routinely available as the ADTC is waiting for further advice from local clinical experts.’</p>	<p>FTeam</p>
11.	<p>GENERAL INFORMATION FROM SCOTTISH MEDICINES CONSORTIUM – DECEMBER 2020 - NONE</p>	
12.	<p>DOCUMENTS FOR INFORMATION</p> <p>ITEM 12.1 (DRUG SAFETY UPDATE NOVEMBER 2020)</p> <p>The Chairman highlighted the article <i>“Modafinil (Provigil): increased risk of congenital malformations if used during pregnancy”</i> noting that modafinil may reduce the effectiveness of oral contraception, is used by students during exams and can be purchased on the internet.</p> <p>The Group agreed that the risk of adverse effects and potential to reduce effectiveness of contraception should be highlighted to students. Professor McLay will take this forward with Aberdeen University and Robert Gordon University.</p>	<p>JMcL</p>

PROTECTIVE MARKING: NONE

ITEM SUBJECT

ACTION

Mrs Harper noted it would also be worth highlighting the information with the Health Village (Sexual Health department) and the main General Practices that students attend.

Items 12.2 (MedWatch newsletter November 2020), 12.3 (Grampian Primary Care Prescribing Group minute September 2020) and 12.4 (Antimicrobial Management Team minute October 2020) were noted.

13. AOCB

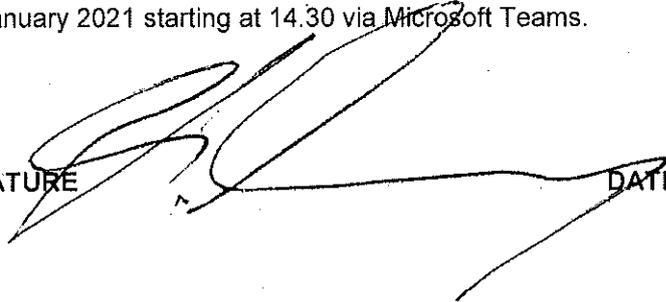
THANK YOU AND GOODBYE

The Chairman reported that Mrs Harper retires from the Formulary Group and NHS Grampian at the end of December 2020. Professor McLay led members in thanking Mrs Harper for the considerable contribution she has given in support of the Formulary Group.

DATE OF NEXT MEETING

Tuesday 19 January 2021 starting at 14.30 via Microsoft Teams.

CHAIRMAN'S SIGNATURE



DATE 19 January 2021