Minutes of the SMC Committee Meeting

Tuesday 01 December 2020

Present:	Dr Mark MacGregor (Chairman) Ms Alison Culpan Dr Jacob Dreyer Ms Clare Dunn Dr Jane Goddard Professor Charlie Gourley Dr Roger Hardman Ms Alex Jones Dr Brian Jones Ms Jennifer Laskey Mr Gordon Loughran Dr Catriona McMahon Dr Scott Muir Dr Avideh Nazeri Dr Robert Peel Ms Yvonne Semple Mr Colin Sinclair Ms Alison Stillie Professor Alison Strath Ms Carla Verschueren
Observers:	Sonia Ziouani Ammor Cristina Coelho Ms Irene Fazakerley Mr Frauke Hunter Miranda Pierre
In Attendance:	Mrs Corinne Booth Ms Ailsa Brown Mrs Jennifer Dickson Mrs Noreen Downes Mrs Gillian Halpin Ms Sharon Hems Ms Kawitha Helme Mrs Donna Leith Mr Iain Leslie Mrs Lindsay Lockhart

	Mrs Pauline McGuire Ms Rosie Murray Mr Jonathan Sim
Apologies:	Dr Paul Catchpole Professor Michael Eddleston Mr Scott Hill Mrs Anne Lee Ms Dionne Mackison Dr Paul Neary Dr Graham Scotland Professor Marc Turner Mr Scott Urquhart Ms Alice Wilson

1.	**Welcome and Apologies for Absence**
1.1	The Chairman welcomed members to the meeting and apologies for absence were noted.
1.2	Welcome to the following observers: • **Sonia Ziouani Ammor,** Pharmaceutical analyst, SMC • **Cristina Coelho**, Lead Pharmacist, NHS Greater Glasgow and Clyde • **Craig Harrower**, Policy Officer, Medicines Licensing, Safety and Regulation, Scottish Government • **Frauke Hunter**, Medicines Regulation, Safety and Licensing Team Leader, Scottish Government • **Miranda Pierre,** newly appointed Research Analyst, SMC **Kawitha Helme**, NDC Lead assessor was also welcomed to the meeting to present agenda item 6.4.
2.	**Declarations of Interest**
2.1	The Chairman reminded members to declare interests in the products to be discussed and the comparator medicines as noted on the assessment reports. It was noted that Healthcare Improvement Scotland have recently refined the policy for handling of Declarations of Interest at meetings. SMC plan to implement the revised policy from January 2021 and therefore when declaring declarations of interest at meetings there is a requirement for members to also indicate whether their interest is financial or non-financial. As before the secretariat will record if members have an interest, however, the substance does not require to be declared as this will be captured in the annual return. The secretariat will distribute the policy to members for information.

3.	**Minutes of the Previous Meeting (03 November 2020)**
3.1	The minutes of the SMC meeting held on Tuesday 03 November 2020 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	Nothing to report.
5	**Chairman's Business**
5.1	Nothing to report.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	entrectinib (Rozlytrek) NSCLC Roche Products Ltd SMC2294 An interest was declared in relation to this product/comparator medicines. Representatives of the submitting company were invited to the committee table to respond to specific queries regarding this submission, comment on matters of factual accuracy and provide clarification on any outstanding issues. Representatives of the Patient Group were invited to the committee table to respond to specific queries regarding the Patient Group submission, and provide clarification on any outstanding issues. The NDC Co Vice Chairman provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. A member of the Public Involvement Team presented a Patient Group submission from Roy Castle Lung Cancer Foundation. Detailed discussion followed and, after a vote of the members, it was decided that entrectinib (Rozlytrek) should be accepted for use within NHSScotland. Indication under review: as monotherapy for the treatment of adult patients with ROS1-positive, advanced non-small cell lung cancer (NSCLC) not previously treated with ROS1 inhibitors. In a phase II study in patients with ROS1-positive advanced NSCLC, the objective response rate was 72%. This advice applies only in the context of an approved NHSScotland 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. The SMC advice will be published on the SMC website on Monday 18 January, 2021.

6.2	<u>fostamatinib (Tavlesse) Instituto Grifols, S.A. SMC2300</u> A personal non-specific declaration of interest was recorded in relation to this product/comparator medicines. Representatives of the submitting company were invited to the committee table to respond to specific queries regarding this submission, comment on matters of factual accuracy and provide clarification on any outstanding issues. Representatives of the Patient Group were invited to the committee table to respond to specific queries regarding the Patient Group submission, and provide clarification on any outstanding issues. The NDC Chairman provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. A member of the Public Involvement Team presented a Patient Group submission from The ITP Support Association. Detailed discussion followed and, after a vote of the members, it was decided that fostamatinib (Tavlesse), should be accepted for restricted use within NHSScotland. Indication under review: treatment of chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments. SMC restriction: for the treatment of patients with severe symptomatic ITP or with a high risk of bleeding who have not had a suitable response to other therapies, including a thrombopoietin receptor-agonist (TPO-RA), or where use of a TPO-RA is not appropriate. Fostamatinib has been shown to be significantly more effective than placebo in raising and maintaining platelet counts at (or above) a minimum target level in previously-treated patients with ITP. This advice applies only in the context of an approved NHSScotland 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. The SMC advice will be published on the SMC website on Monday 18 January, 2021.
6.3	<u>daratumumab (Darzalex) Janssen-Cilag Ltd SMC2302</u> No interests were declared in relation to this product/comparator medicines. Representatives of the submitting company were invited to the committee table to respond to specific queries regarding this submission, comment on matters of factual accuracy and provide clarification on any outstanding issues. Representatives of the Patient Group were invited to the committee table to respond to specific queries regarding the Patient Group submission, and provide clarification on any outstanding issues.

	The NDC Co-Vice Chair provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. A member of the Public Involvement Team presented a Patient Group submission from Myeloma UK Detailed discussion followed and, after a vote of the members, it was decided that daratumumab (Darzalex), should be accepted for use within NHSScotland. Indication under review: in combination with bortezomib, thalidomide and dexamethasone, for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant. The addition of daratumumab to bortezomib, thalidomide and dexamethasone was associated with a significant improvement in stringent complete response rates in patients with newly diagnosed multiple myeloma who were eligible for autologous stem cell transplant. This advice applies only in the context of an approved NHSScotland 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. The SMC advice will be published on the SMC website on Monday 18 January, 2021.
	RESUBMISSION
6.4	<u>melatonin (Slenyto) Flynn Pharma Ltd SMC2306</u> No interests were declared in relation to this product/comparator medicines. Representatives of the submitting company were invited to the committee table to respond to specific queries regarding this submission, comment on matters of factual accuracy and provide clarification on any outstanding issues. Representatives of the Patient Groups were invited to the committee table to respond to specific queries regarding the Patient Group submissions, and provide clarification on any outstanding issues. The NDC Lead Assessor provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. A member of the Public Involvement Team presented Patient Group submissions from ADHD Parent Support West Glasgow and The Smith-Magenis Syndrome (SMS) Foundation UK. Detailed discussion followed and, after a vote of the members, it was decided that melatonin (Slenyto) should not be recommended for use within NHSScotland. Indication under review: Treatment of insomnia in children and adolescents aged 2 to 18 years with autism spectrum disorder and / or Smith-Magenis syndrome, where sleep hygiene measures have been insufficient. Melatonin prolonged-release (Slenyto), compared with placebo, increased total sleep time and sleep onset latency in children aged 2 to 17.5 years with sleep problems and autism

	spectrum disorder and / or Smith-Magenis syndrome who had an insufficient response to sleep hygiene measures. The company did not present a sufficiently robust economic analysis to gain acceptance by SMC. The SMC advice will be published on the SMC website on Monday 18 January, 2021.
7.	**Forthcoming Submissions**
7.1	Noted
8.	**Area Drug & Therapeutics Committee (ADTC) Issues**
8.1	Nothing to report.
9.	**Any Other Business**
9.1	Nothing to report.
10.	**Closed Session**
	NON SUBMISSIONS
10.1	apalutamide 60mg film-coated tablets (Erleada) Janssen-Cilag Ltd SMC2323 In the absence of a submission from the holder of the marketing authorisation apalutamide (Erleada) is not recommended for use within NHSScotland. Indication under review: in adult men for the treatment of metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland. The SMC advice will be published on the SMC website on Monday 18 January, 2021.
10.2	dupilumab 300mg solution for injection in pre-filled pen and 300mg solution for injection in pre-filled syringe (Dupixent) Sanofi Genzyme SMC2324 In the absence of a submission from the holder of the marketing authorisation dupilumab (Dupixent) is not recommended for use within NHSScotland. Indication under review: As an add-on therapy with intranasal corticosteroids for the treatment of adults with severe chronic rhinosinusitis with nasal polyposis for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.

	The SMC advice will be published on the SMC website on Monday 18 January, 2021.
10.3	talazoparib 0.25mg/1mg hard capsules (Talzenna) Pfizer Ltd SMC2325 In the absence of a submission from the holder of the marketing authorisation talazoparib (Talzenna) is not recommended for use within NHSScotland. Indication under review: As monotherapy for the treatment of adult patients with germline BRCA1/2 mutations, who have HER2-negative locally advanced or metastatic breast cancer. Patients should have been previously treated with an anthracycline and/or a taxane in the (neo) adjuvant, locally advanced or metastatic setting unless patients were not suitable for these treatments. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine-based therapy, or be considered unsuitable for endocrine-based therapy. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland. The SMC advice will be published on the SMC website on Monday 18 January, 2021.
11.	**Decisions**
11.1	The voting poll was launched and members voted on each of the medicines considered. The decision for each medicine was reported.
12.	**Any Other Business in Closed Session**
12.1	**Update on fast track approach**
	This is a pragmatic approach to minimise delay in patient access as a result of the COVID-19 pandemic and applies to a small number of medicines following review by the SMC executive. Fast tracked advice for four medicines, two full and two abbreviated submissions will be issued in confidence to Boards on Friday 04 December 2020, and published on Monday 18 January 2021. • secukinumab 150mg solution for injection in pre-filled syringe and 150mg solution for injection in pre-filled pen (Cosentyx) Novartis Pharmaceuticals UK Limited SMC2308 Accepted for use for the treatment of active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein and/or magnetic resonance imaging evidence in adults who have responded inadequately to non steroidal anti inflammatory drugs. • brentuximab vedotin 50mg powder for concentrate for solution for infusion (Adcetris) Takeda UK Ltd SMC2310 Accepted for use in combination with cyclophosphamide, doxorubicin and prednisone (CHP) for adult patients with previously untreated systemic anaplastic large cell lymphoma (sALCL).

	• brigatinib 30mg, 90mg and 180mg film-coated tablets (Alunbrig) NSCLC Takeda UK Ltd SMC2314 Accepted for use as monotherapy for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer previously not treated with an ALK inhibitor. • daratumumab 1,800mg solution for subcutaneous injection (Darzalex) Janssen-Cilag Ltd SMC2326 Accepted for use in combination with bortezomib, thalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant.
12.2	**New regulatory arrangements for medicines from 1 January 2021**
	A presentation providing an update regarding new regulatory arrangements for medicines from 1 January 2021 was provided.
13.	**Date of the Next Meeting**
13.1	The date of the next meeting was confirmed as Tuesday 12 January, 2021.