Drug and Therapeutics Committee – Minutes – Confirmed

Date / Time	Thursday 13th December 2018 8:15am – 10:00am
Venue	The Committee Room, Alderson House, HRI
Chair	Prof A Morice, Chair, Professor of Respiratory Medicine
Notes / Action Points	Mrs W Hornsby, Senior Pharmacy Technician
Quorate: Yes / No	Yes
Attendance	Mr S P Gaines, Professional Secretary, Senior Principal Pharmacist – Clinical Services
	Mr P O'Brien, Deputy Chief Pharmacist (until 9.20am)
	Mr D Corral, Chief Pharmacist, Clinical Director Therapy & Therapeutics (until 9.20am)
	Mr K McCorry, Medicines Optimisation Pharmacist, NECS (via speakerphone until 9.30am)
	Dr S Raise, GP ER CCG (via speakerphone until 9am)
	Dr A Samson, Infectious Diseases Consultant
	Prof M Lind, Vice Chair, Professor of Oncology
	Dr F Umerah, Consultant Anaesthetist
	Dr H Klonin, Consultant Paediatrician
	Dr O Ogunbambi, Consultant Rheumatologist
	Mr R Kapur, Vascular Surgeon
Guests	Dr A Ming, Consultant Neurologist
	Dr J Harley, Consultant Neurologist
	Dr S Jose, Consultant Paediatrician (until 9.15am)
	Mr A Carter, Pre-Registration Pharmacist, Miss J Wenyika, Pre-Registration Pharmacist
	Mr A Cunliffe, Pre-Registration Pharmacist, Miss C Loftallah, Pre-Registration Pharmacist
	Mr L Tan, Pre-Registration Pharmacist, Miss S Chamba, Pre-Registration Pharmacist
	Mr D Passasseo, Pre-Registration Pharmacist
	Miss L Dunnachie, Pre-Registration Pharmacist

Agenda No	Item	Discussion	Decision Made	Action	Lead	Due Date	Progress /Date Closed
2018.12.01	**Apologies**	None.					
2018.12.02	**Declarations of Interest**	None.					12/18
2018.12.03	**Minutes of the previous meeting**	KMcC asked that page 4 be clarified as follows: *KMcC explained that the main reason that both CCGs came to this decision was related to awaiting the final NICE TA outcome; the NICE clinical evidence review; NICE place in therapy recommendation and NICE cost effectiveness review. KMcC explained that the HEY summary, D&T submission and HEY pharmacy review all went to each of the CCG committees. One of the CCGs had also highlighted the RMOC guidance on FOC medicines.* KMcC also asked that the paragraph relating to lidocaine and AREDS be altered to reflect the fact that the decisions related to Hull CCG, so both CCGs would now be the same.	KMcC to send clarification text to AM for approval & entry in minutes. WH to amend minutes.	KMcC to send suggested text to AM WH to amend	KMcC WH	01/19 01/19	
2018.12.04	**Action Tracker**	**Tracker** ML to submit application for atezolizumab TA520. **New Process for Oncology Requests** Review form in six months. **New Process for Oncology Requests** POB to discuss amendments with SS. **NICE Guidance** ML to request application for atezolizumab TA525. **AOB – Out of Hours Flowchart** DC to discuss funding with CS HG. **NICE Guidance** ML to request application for atezolizumab in line with NICE	Ongoing. Ongoing. Ongoing. Ongoing. Ongoing. Ongoing.		ML SS/SG POB ML DC ML	8/18 1/19 11/18 8/18 11/18 9/18	

		TA492.					
		NICE Guidance ML to request application for niraparib in line with NICE TA528.	Ongoing.		ML	9/18	
		MHRA DSU DC has asked JM to prepare a Yellow Card Scheme banner, to send to web services, to be added to Pattie.	Action complete.				12/18
		NICE Guidance TA535 Lenvatanib has been added to rear of formulary - available via chairs approval.	Action complete.				12/18
		NICE Guidance TA539 Lutetium ML to request application. It has been established from SS that this item would not be used by HEY, so application not required.	WH to add to rear of formulary as "not used at HEY".	WH to amend formulary	WH	1/19	
		Tracker - Erenumab DC to request opinion of medical directors and HEY commissioning team. AM advised that he would be happy to attend a meeting to discuss and as a representative of D&TC.	Meeting has not yet taken place.	Feedback next time	DC	12/18	
		Tracker - Erenumab WH to add RMOC FOC scheme document to Dec/18 agenda.	On agenda for discussion.	Action complete			12/18
		Tracker AM has written to HEY colleagues regarding prescribing of lidocaine plasters and AREDs.	Action complete.				12/18
		NEW Product Requests AM has written to applicants and WH has updated formulary.	Action complete.				12/18
		NICE Guidance TA543 Tofacitinib - WH has updated formulary as "In line with NICE".	Action complete.				12/18
		SMPC Minutes – adding patient allergies DC has arranged a meeting to discuss this with the Lorenzo pharmacist.	Action complete.				12/18

		AOB AM still to write to main users of Radium regarding alert. **AOB** JM has arranged a new product request for Epidolex, which is on the agenda for discussion.	AM to write to main users. Action complete.	Ongoing	AM	12/18	 12/18
2018.12.05	**New Product Requests**	**Cannabidiol Oral Solution (Epidiolex®) – Dr S Jose** The application was for the cannabidiol (CBD) product "Epidiolex" which is licensed in the USA but not the UK. The request was for the treatment of epilepsy which has proven intractable to treatment with conventional licensed anti-epileptic drugs given at therapeutic doses in children. The product has been made available by the manufacturer as a compassionate use scheme to specialist centres. Dr Jose is working jointly with Leeds specialist centre, who visit Hull to do a joint clinic monthly. The compassionate scheme is only available to 125 patients across 25 specialist centres around the country. Therefore it is thought it will only be available to approximately 5 patients via Leeds. Hull was only likely to represent 1 or 2 of these 5 patients. SR asked if there would be any impact on GPs being asked to prescribe the product in emergency situations. Dr Jose assured him that it was not a GP issue and that patients would be advised to contact the paediatric specialist team for repeat supplies. The product would be "RED" as it was an unlicensed product in the UK. Two key papers were discussed as evidence: one from the Lancet 2018 and one from the New England Journal of Medicine 2018. The drug used in both trials was purified CBD. Dr Jose pointed out that products used to treat the patients which have received large amounts of media attention were not necessarily pure CBD/Epidiolex and that these products may contain both CBD and tetrahydrocannabinol (THC). Dr Jose explained to the committee that the MDT, including a tertiary paediatric neurology specialist from Leeds would expect to follow the British Paediatric Neurology Association (BPNA) national "Guidance on the use of cannabis-based products for medicinal use for children and young people with epilepsy", issued 31/10/2018. It	Dr Jose will send copy of protocol to AM as correspondence to demonstrate the procedure followed. Approved for addition to formulary.	Protocol to be sent to AM AM to write to applicant WH to update formulary	JS AM/ WH	01/19 01/19	

		recommended at 5.1 that patients were referred to tertiary services, and at 5.2 that a non-licensed cannabis-based product for medicinal use be used as a treatment of last resort for children who meet 3 criteria: 1) Have an epilepsy that has proven intractable to treatment with conventional licensed anti-epileptic drugs at therapeutic doses. 2) Have not responded to the ketogenic diet or for whom the diet is inappropriate. 3) Are not candidates for epilepsy surgery. Epidiolex would be considered for patients who had not responded to at least 2 conventional drugs and met the above criteria. NICE guidance is due to be published in October 2019 and it is believed NHSE will produce commissioning guidance in April 2019. The committee discussed if they felt the product was safe. Dr Ming raised the issue of teratogenicity and effects on reproduction. Although initially this wouldn't be a problem, as the application was for children, eventually it would become an issue as they became young adults. There was currently no adequate data available in pregnant women. The American Prescribing Information (UK SmPC equivalent) does not contain any information relating to safety in pregnancy. Regarding efficacy, the 2 published trials in 2018 were short term, over 14 weeks. The efficacy in the studies was judged by parental reporting of reduction in seizures. The efficacy was demonstrated to be similar to new and known anti convulsive agents. The committee noted that there was a very limited amount of places on the compassionate use scheme and therefore if further patients qualified for treatment it would have to be met by the F&W Health Group until April 2019, when it was anticipated that NHSE would then take on funding. It is believed the company will withdraw the compassionate scheme once the product receives a license in the UK. BPNA Guidance recommends that treatment be started on a named patient basis where the chair of the D&TC and HG					

		medical director are in agreement treatment can commence and that patient has been reviewed and the BPNA criteria met. The committee then commenced a discussion around the use of cannabis related agents in adults. Dr Harley pointed out that there are issues around the availability of different agents. Patients in high profile media cases had been treated with products containing THC which requires approval from the home office. MS, chronic pain, epilepsy and headaches are all indications which received media attention recently. The trust position on these conditions is clear, and in line with the national guidance documents circulated, that as there is no reasonable clinical evidence or safety information available it would be clinically inappropriate to prescribe for these conditions. Information on the stability and content of preparations containing both THC and CBD is unknown, unlike Epidiolex and Sativex which are licensed products. The committee supports national guidance relating to the use of cannabis-related products in the treatment of Lennox-Gaustaut Syndrome and Dravet Syndrome and will await publication of national guidance for use in adults before making any further decisions. **Sodium Zirconium Cyclosilicate (Lokelma) – Hyperkalaemia – Prof Bhandari** The committee felt that the evidence presented did not demonstrate better efficacy than calcium resonium. KMcC said that NICE had published a consultation document in October/18: https://www.nice.org.uk/guidance/gid-ta10307/documents/appraisal-consultation-document which did not recommend the product. **QV Range – Emollients – Dr R Zaman** No robust evidence provided with the application. KMcC advised the committee that NHSE/Clinical Commissioners had published joint consultation guidance in November/18: https://www.engage.england.nhs.uk/consultation/items-routinely-prescribed-update/user_uploads/low-priority-prescribing-consultation-guidance.pdf, recommending that bath and shower emollient preparations should not be routinely prescribed. Therefore the committee agreed to defer the application and to add this paper to the January/19 agenda for discussion.	Rejected. Deferred until joint guidance reviewed.				

		Nivolumab – Melanoma Stage III and IV - Prof Maraveyas Approved.	Approved.				
2018.12.06	**NICE Guidance**	**NICE Guidance:** **October 2018** • NG109 Urinary tract infection (lower): antimicrobial prescribing. • NG110 Prostatitis (acute): antimicrobial prescribing. • NG111 Pyelonephritis (acute): antimicrobial prescribing. • NG112 Urinary tract infection (recurrent): antimicrobial prescribing. • NG35 Myeloma: diagnosis and management Update. • TA293 Eltrombopag for treating chronic immune (idiopathic) thrombocytopenic purpura (Update). • TA221 Romiplostim for the treatment of chronic immune (idiopathic) thrombocytopenic purpura (Update). • CG54 Urinary tract infection in under 16s: diagnosis and management. **November 2018** • NG88 Heavy menstrual bleeding: assessment and management. • TA545 Gemtuzumab ozogamicin for untreated acute myeloid leukaemia. • TA546 Padeliporfin for untreated localised prostate cancer (Not recommended). • TA 547 Tofacitinib for moderately to severely active ulcerative colitis. On formulary as per NICE TA. • NG113 Urinary tract infection (catheter-associated): antimicrobial prescribing.	All on formulary. All on formulary. All on formulary. All on formulary. Noted. On formulary. On formulary. All on formulary. All on formulary. Not on formulary. Not NICE recommended. AM to write to Gastroenterology for application All on formulary.	ML to seek application AM to write	ML AM	01/19 01/19	
2018.12.07	**MHRA Drug Safety Update**	November 2018	Not discussed.	Add to Jan agenda			
2018.12.12	**Minutes from SMPC**	September	Not discussed	Add to Jan agenda			
2018.12.12	**Minutes from HERPC**	September	Not discussed	Add to Jan agenda			

2018.12.12	**Correspondence Received**	None					12/18
2018.12.13	**Regional Medicines Optimisation Committee**	• South RMOC update Nov 18 • Homely Remedies Position Statement • Homely Remedy Template Policy • Guidance Prescribing of Liothyronine • Pharmacy & Medicine Optimisation Newsletter • New Product Evaluations • Link to STOMP Resources	Not discussed	Add to Jan agenda			
2018.12.14	**Chairs approvals**	Riboflavin – Riboflavin Transporter Deficiency – Dr Nandakumar	Not discussed	Add to Jan agenda			
2018.12.15	**Issues to escalate to OQC**	None					12/18
2018.12 16	**Any Other Business**	None					12/18
2018.12 17	**Date and Time of Next Meeting**	Thursday10th January – 8.15 – 9.30am, Meeting Room 3, Women's & Childrens, HRI.					