EPSOM AND ST HELIER UNIVERSITY HOSPITALS NHS TRUST

NEW DRUG AND INTERFACE GROUP

MINUTES OF THE MEETING HELD ON WEDNESDAY 13th June, 2018 12.30 – 2.00pm
in the Board Room, Ferguson House, St Helier Hospital

Present:
Dr V De Silva (Chair) **VDS**
Sarah Taylor (Chief Pharmacist, Sutton CCG) **ST**
Liz Clark (Lead Commissioning Pharmacist, Surrey Downs CCG) **LC**
Lynn Ring (Consultant Nurse Glaucoma) **LR**
Dr J Wang (Consultant Medical and Renal) **JW**
Anne Lowson (Secretary) **AL**
Dr M Gardner (Consultant Anaesthetist) **MG**
Dr R Shephard (Consultant Neonatologist) **RS**

In attendance:
Miss R Viswanatha (Consultant Obstetrics and Gynaecology) **RV**
Sumbo Adeyemo (Medicines Management Pharmacist) **SA**
Kuljit Gata-Aura (Medicines Management Technician) **KGA**
Helen Parnell (Respiratory Nurse Specialist) **HP**
Maria D'Sa (Pharmacy and Medicines Management Administrator) **MD**

No	Item	Responsible for Action
1.	**Apologies for Absence** Anne Davies (Chief Pharmacist) **AD** Dr Justin Bendig (Consultant Microbiologist) **JB** Dr S Moodie (Consultant Gastroenterologist) **SM** Dr A Mahmood (Consultant Gastroenterologist) **AM**	
2.	**Declarations of Interest** Nil for the meeting.	
3.	**Minutes of the Meeting held on 7th February 2018** The minutes of the meeting held on 11th April 2018 were agreed.	
4.	**Matters Arising** **Venous Thromboembolism** No response from surgery or haematology as yet. EOC are reviewing the recommendation to use aspirin for VTE prophylaxis post-op for total knee replacements. Patients would be discharged with aspirin 75mg twice daily for 2 weeks. Medical council are considering this request and a final document will be sent to Medicines Management prior to adoption.	**AL**
5.	**New Drug Requests**	
	a) Mysodelle®- Vaginal delivery system Miss Viswanatha presented the case for using misoprostol 200mcg vaginal delivery system for induction of labour in women with an unfavourable cervix from 36 weeks gestation in whom induction is clinically indicated. The request is based on the fact that it will improve patient satisfaction and reduction in duration of induction to delivery time with no increase in caesarean section rate. Prolonged labour is associated with higher infection rates, greater use of antibiotics, increased maternal distress and more use of oxytocin and hospital resources. The Trust is currently using dinoprostone vaginal tablets or pessaries. Evidence from the EXPEDITE phase 3 double blind randomised multi-centre study compared misoprostol controlled release vaginal insert and 10mg dinoprostone controlled release vaginal inserts.	

	Statistically significant improvements were seen in time to vaginal delivery, reduced by 11.3 hours by misoprostol compared with dinoprostone. The median time to active labour was reduced by 6.5 hours and the proportion of women requiring pre-delivery oxytocin reduced by 26% in women receiving misoprostol vaginal insert compared with the dinoprostone vaginal insert. However, the rate of uterine tachysystole with category II and III foetal heart rate changes or tachysystole requiring intervention was three times higher with the misoprostol vaginal inserts compared with dinoprostone vaginal inserts. An MHRA alert published in Feb 2018 reports excessive uterine contractions (tachysystole) unresponsive to tocolytic treatment and have made recommendations to monitor patients closely and remove the misoprostol vaginal insert if: -Tachysystole - more than 5 contractions in a 10 minute window, -Prolonged contractions - single contractions lasting 2 minutes or longer -Hypertonic contractions or there is clinical concern for mother or baby. It was noted that dinoprostone (Propess®) is only licensed from 38 weeks gestation and is therefore often being used outside the licence. Miss Viswanatha advised that it would initially be used at Epsom and usage audited. This will include the usage of concomitant drugs e.g. Syntocin to see if Mysodelle reduces the side effects and improves patient satisfaction. The results of the audit will be compared with current audits. Education of Staff will be important especially in relation to the side effects. Miss Viswanatha felt that she could deliver this and advised Queen Charlotte Hospital would also be able to provide support. Ferring pharmaceuticals have currently offered a price reduction for 20 packs (100 inductions). After this the price would need to be renegotiated. This price to be confirmed by pharmacy. **Decision** Mysodelle® to be added to the formulary for use 1st line in low risk inductions at 36 – 38 weeks where the foetus is well grown and Bishop score <4. Use in Epsom to be rolled out first as the education required is time consuming. Audit to be carried out taking approx. 6 months and data reviewed at a future Medicines Management meeting. A discounted price for the Mysodelle® has been negotiated for a trial period; however the details of this will require confirmation. **b) Trimbow® inhaler – COPD (triple therapy)** This is an MDI containing beclomethasone, formoterol and glycopyrronium (an inhaled steroid (ICS), long acting B_2 agonist (LABA) and long acting muscarinic antagonist (LAMA)) and is licensed for maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of ICS/LABA. It can be used with the Aero Chamber Plus spacer device. Studies have found small statistically significant improvements in lung function (FEV_1) rates of moderate to severe exacerbations of COPD and quality of life with Trimbow® compared with beclomethasone / formoterol (Fostair)® or indacaterol / glycopyrronium (Ultibro ® Breezhaler) dual therapy or tiotropium alone. NICE COPD guidelines (2010) recommend triple therapy in people who remain	**SA / KGA** **SA**

	breathless or have exacerbations despite using an ICS / LABA (add a LAMA) or a LAMA (add an ICS / LABA) irrespective of FEV_1. This was published before any of the LABA /LAMA or ICS /LABA/LAMA combination inhalers were available in the UK. GOLD 2017 advises triple therapy is reserved for patients who continue to have frequent exacerbations leading to hospital admission despite dual bronchodilation with LABA/LAMA combination. NICE have recently produced an evidence review on Trimbow® and advise taking safety efficacy cost and patient factors into account when considering the place in therapy. They suggest it for moderate to severe COPD patients who have found triple therapy beneficial using more than 1 inhaler and can use a pressurised metered dose inhaler (with or without a spacer) but find their current medication regime difficult or confusing and are having trouble complying with treatment. There are other triple therapies e.g. Trelegy® but this is a dry powder device so can't be used with a spacer. The committee discussed the importance of compliance with treatment and that certain patients may benefit from using just one inhaler. It was recognised that it is currently not licensed as a step up from LABA/LAMA dual therapy and that it is a fixed dose combination which does not allow for dose adjustment. Trimbow® is cheaper than using two separate inhalers concurrently to achieve the same combination. **Decision** Trimbow ® was approved in line with the licenced indications in moderate to severe COPD not adequately controlled on an ICS / LABA inhaler combination. (Note that use of Trimbow® as step up from LABA / LAMA dual therapy would be off label). For initiation by respiratory specialists only. The license may change in future. Considerations on initiating therapy include use of device and finding current medication regimen difficult or confusing and are having trouble complying with treatment. Surrey Downs CCG will take the minutes and decision as a request for consideration at the PCN. **c) Formulary additions** **I. Isoprenaline – Bradycardia/peri-arrest** Isoprenaline has been requested to be added back onto the Trust formulary for peri-arrest arrhythmias/bradycardia. It was removed from the formulary previously due to manufacturing issues. It is now more available and is recommended as a treatment option for bradycardia by The Resuscitation Council (UK). **Decision** To re-add Isoprenaline injection to the formulary for use in line with the Resuscitation Council (UK) adult bradycardia algorithm. **II. Sildenafil- Penile rehabilitation** The Trust urologists have been using phosphodiesterase type 5 inhibitors (PDE 5i) for penile rehabilitation following prostatectomy for many years and the Trust will supply the full course until efficacy is established. However there is no formulary statement to support this usage. The evidence for its use was presented in the UKMi document. **Decision** To add a statement to the formulary to highlight that sildenafil was the PDE5i of choice for penile rehabilitation. The expected dose range is 25-100mg up to three times a week and 3-6 months may be necessary to establish efficacy. If it is helping	**AL / KGA** **AL / KGA**

	treatment should be continued for 24-36 months. **III. Ferrinject®- Heart failure (HF)** Iron deficiency is common in heart failure and it can lead to anaemia and/or skeletal muscle dysfunction without anaemia. Two RCT's (CONFIRM HF and FAIR HF) have shown that IV ferric carboxymaltose improves quality of life and NYHA class over 6 months, and in the CONFIRM HF study exercise capacity improved and reduced HF hospitalizations. Ferrinject® is already on the Trust formulary for use by other specialities in outpatient settings. This is due in part to its shorter administration time. **Decision** Ferrinject ® to be allowed for use by cardiologists for the treatment of heart failure in outpatients only. (in line with other specialities) Cosmofer® will remain available for in patient use.	**AL / KGA**
6.	**Six Month New Drug Reviews** Nothing for this meeting.	
7.	**NICE/MHRA Guidance**	
	I. MHRA Guidance - April 2018 The drug safety update for April included advice on the pregnancy prevention programme for valproate medicines. This advice has been circulated to the paediatricians, neurologists and Dr Bolton; awaiting response. It will be discussed at MMCBG meeting in July. Obeticholic acid (Ocaliva▼) and the risk of serious liver injury in patients with pre-existing moderate or severe hepatic impairment has been circulated to the gastroenterologists. **II. MHRA Guidance - May 2018** The drug safety update for May mentioned again about valproate medicines and the pregnancy prevention programme. Braltus® (tiotropium) risk of inhalation of capsule if placed in the mouthpiece of the inhaler has been circulated to the respiratory clinicians and communicated to pharmacy staff.	**KGA** **KGA**
	Technology Appraisals for Discussion	
	a) Avelumab for treating metastatic Merkel cell- TA517 Avelumab will be added to the formulary for treatment of and metastatic Merkel cell carcinoma. The Trust will not initiate treatment **b) Tocilizumab for treating giant cell arteritis- TA518** Tocilizumab will be added to the formulary for treating giant cell arteritis. It is PbR excluded and access to the drug will by via the BlueTeq system Funding via the CCG. **c) Pembrolizumab for treating locally advanced or metastatic urothelial carcinoma after platinum-containing chemotherapy - TA519** Pembrolizumab will be added to the formulary for treating locally advanced or metastatic urothelial carcinoma after platinum containing chemotherapy. The Trust will not initiate treatment. **d) Atezolizumab for treating locally advanced or metastatic non-small-cell lung cancer after chemotherapy – TA520** Atezolizumab will be added to the formulary for treating locally advanced or metastic non-small cell lung cancer after chemotherapy. The Trust will not initiate treatment.	**KGA** **KGA** **KGA** **KGA**
	Technology Appraisals Terminated	
	e) None for this meeting.	
	Technology Appraisals for Information	
	f) None for this meeting.	

	Technology Appraisals Not Recommended	
	g) None for this meeting.	
	Clinical Guidelines Updated for Information	
	h) Depression in adults: recognition and management (updated) - CG90 These guidelines have been amended to link with the MHRA's latest advice and resources on sodium valproate. **i) Epilepsies: diagnosis and management - CG137** These guidelines have been amended to link with the MHRA's latest advice and resources on sodium valproate. **j) Neuropathic pain in adults: pharmacological management in non-specialist settings - CG173** These guidelines have been amended to link with the MHRA's latest advice and resources on sodium valproate. **k) Bipolar disorder: assessment and management - CG185** These guidelines have been amended to link with the MHRA's latest advice and resources on sodium valproate. **l) Antenatal and postnatal mental health: clinical management and service guidance - CG192** These guidelines have been amended to link with the MHRA's latest advice and resources on sodium valproate.	**KGA / AL**
	Clinical Guidelines for Discussion	
	m) Lyme disease - NG95 The microbiologists have supported the guidance and do not feel it raises any issues.	**KGA / AL**
	Clinical Guidelines for Information	
	None for this meeting.	
	Quality Standard Updated	
	None for this meeting.	
	Quality Standard for Discussion (medicine related issues only)	
	n) Cystic fibrosis – QS168 The Trust formulary reflects the required medications detailed in the quality standard.	**KGA / AL**
	Quality Standard for Information	
	None for this meeting.	
	Highly Specialised Technologies Guidance	
	None for this meeting.	
	Highly Specialised Technologies for Discussion	
	o) Technology Appraisal 507: Sofosbuvir–velpatasvir–voxilaprevir for treating chronic hepatitis C These drugs will be added to the formulary for use in treating chronic hepatitis C and will be initiated by delivery networks in line with NHS England guidance**.** **p) NICE Technology Appraisal Final Appraisal Determination**: **Pembrolizumab for treating locally advanced or metastatic urothelial carcinoma after platimum-containing chemotherapy** For information as the Trust is not a recognised centre for treatment. **q) NICE Technology Appraisal 496**:**Ribociclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative locally advanced or metastatic breast cancer** For information as the Trust is not a recognised centre for treatment. **r) NICE Technology Appraisal 495**:**Palbociclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer** For information as the Trust is not a recognised centre for treatment.	

	s) NICE Technology Appraisal 500:**Ceritinib for untreated ALK-positive non-small-cell lung cancer** For information as the Trust is not a recognised centre for treatment.	
	Health Technology Assessment	
	For Discussion	
	None for this meeting.	
8.	**Revised national guidance on 'Responsibilities for Prescribing between Primary and Secondary/Tertiary Care'**	
	No update for this meeting.	**AD**
9.	**Patient Safety Alerts**	
	None for this meeting.	**AD**
10.	**Operational Issues**	
	a) Cow's Milk Protein Allergy The proposals made at the last meeting have been discussed with the paediatricians and they commented that they feel Nutramigen® should remain an option as an extensively hydrolysed formula. The patients seen in hospital are generally more severe and clinicians have been made aware of situations where vulnerable children have not been able to access appropriate products. It was therefore agreed that Nutramigen® would be added as third line together with Aptamil Pepti® and Aptamil Pepti® (from 6 months). Third line agents will only be prescribable by dietician or consultant paediatricians. An order set on ePMA will be devised to help the prescribers identify 1st, 2nd and 3rd line agents. It was recognised that some initiation is done in A&E and education about the changes would be needed. LR advised she will link with Craig Wood to rule out the changes to nurses in A&E. All clinicians will be advised to inform the GP of the reason for product choice in the clinic letters. Agreed products will be: ❖ Amino Acid Formulas ➢ First line: SMA Alfamino® ➢ Second line: Neocate® ❖ Extensively Hydrolysed Formulas ➢ First line: Similac Alimentum® (Casein – based) ➢ Second line: SMA Althera® (contains lactose) ➢ Third line: Aptamil Pepti® and Aptamil Pepti®(from 6 months contains lactose) ➢ Nutramigen® and Nutramigen® (Lactose free) Third line agents for initiation by dietician or consultant paediatrician only	**KGA / AL**
	b) Anti- Reflux Formula Recently the Trust paediatricians have been informed that GP's in Sutton and Merton will not supply Enfamil AR® which thickens milk formulae in the stomach and contains corn starch. PrescQIPP have previously advised that specialist infant formula should be purchased over the counter as they are a similar cost to milk formula. This includes Enfamil AR® which is used for gastro oesophageal reflux disease (GORD). Enfamil AR® reacts with the stomach acids to thicken and should not be used in conjunction with separate thickeners or with medication such as ranitidine or proton pump inhibitors. Although the CCG's have advised that anti reflux formula should not be prescribed in their guidance and there has been an education programme to promote this recently, the paediatricians are concerned that certain babies particularly small pre-term babies may be at risk if families are not able to purchase Enfamil AR®. These cohorts are often weaned earlier particularly if Enfamil AR® doesn't work. Infant Gaviscon slightly thickens feeds but the sodium content should be considered. ST and RS to discuss exceptions to this advice outside of the meeting and outline a	

	specific patient cohort for whom GPs will be able to prescribe Enfamil AR® to ensure continuity of care.	
	a) Regional Medicines Optimisation Committees **I. London Minutes- March 2018 – for information** For information only. **II. Position Statement- Antidotes and Rarely Used Medicines** RMOC (London) reviewed issues relating to access to pan regional antidotes and other rarely used medicines (RUM's). RMOC will prepare a document by July 2018. **III. Midlands and East Update- April 2018** Minutes for information. RMOC will produce guidance on safety factors to be considered during local formulary decision making when discussing insulin preparations. **IV. Adalimumab Briefing paper- Final March 2018** Biosimilar adalimumab will be available later in the year. The Trust will be in a position to start switching patients in December once the framework for London is published. An initial meeting with Trust Consultants to be arranged. A patient information leaflet will be written. Gain shares to be discussed with the CCG's. **v. Implementing Shared Care Guidance – primary/secondary care interface (South of England)** The South RMOC is interested to understand the shared care processes across the South of England and particularly to be aware of the areas / medicines that can create difficulties at the interface. Comments to be feedback by 15/7/18 to AL to be discussed at MMCBGM.	
	b) Patient information leaflet – Supplies of Medication No update for this meeting	**AD**
	c) Constipation in adults guidelines for information Final version for information.	**DB / KGA**
	d) NHSE guidance on OTC and self- care prescribing This document advices conditions for which over the counter items should not routinely be prescribed in primary care. It is important that the providers give a consistent message about the availability of medication over the counter for self-limiting conditions. Need to work with A&E. Primary care are developing posters to advise patients and these will be shared with secondary care once completed. This will be discussed further at MMCBG meeting.	**AD**
11.	**Feedback from CCGs and Trust Committees**	
	a) Respiratory Working Group The posters devised by Sutton CCG and the Trust regarding management options for adult COPD and asthma will be launched in September 2018. The SWL Alliance Respiratory group which includes Sutton CCG is currently developing joint asthma and COPD guidance. NICE COPD guideline update is expected later on this year and a decision needs to be made to wait or continue to develop joint interim guidance for COPD. **I. DOACs (Surrey preferred options)** The Trust has signed a contract for the price of edoxaban.	**SA** **AD**
	b) Sutton & Merton CCGs **I. Minutes-March 2018** Minutes for information. **II-VII. Documents for information** These interface prescribing documents have minor updates but any comments to be sent to AD by the end of this week.	**AD**

	VIII. The Management of Uncomplicated Constipation in Adults For information. These were used as the base for the Trust guidelines. **IX-XIV. Documents for information** These pathway guidelines for GP's have been devised by GP's and Dr Pritash Patel (Consultant Gastroenterologist) and the committee supported them. To clarify with Dr Patel whether they might also be useful to Trust staff e.g. A&E or UCC.	**KGA / AL**
	c) SWL Medicines Optimisation Group **I. Quick Reference PNS Supplement Guidance for Dietitian Reference** Awaiting response from Trust dietician. It was noted that they are similar to previous versions. Contract limitations are reflected in product choice in primary and secondary care. ST to link with Gillian Thorpe (Trust Lead Dietician).	**AL/ST**
	e) SWL Cardiovascular Group for Discussion Nothing for this meeting.	
	f) Surrey Prescribing Clinical Network **I. Minutes-May 2018** Minutes for information. **II. Vitamins and minerals (excluding prescription only vitamin D analogues)** Work on going on this document regarding formulary availability of vitamins and minerals. Update at next meeting. **III. Management of Seasonal Allergic Rhinitis (Hay Fever)** For information; the Trust have the treatment options available on formulary. **IV. Continuous Glucose Monitors (CGM) and consumables** CGM and consumables are not on the list of high cost devices and listed procedures schedule and so the cost should be met by the providers within current national tariff payments. The diabetic teams are discussing how to manage this cost pressure within the division. Currently, for children, each request is being made via the one off drug request process and assessed individually by the Paediatric Divisional Team. **V. Ulipristal (Esyma) for the treatment of uterine fibroids** The Trust supports this policy statement and has removed ulipristal (Esyma®) from the formulary. **VI. Bone morphogenic protein** For information. **VII. Botulinum toxin type A for the prevention of headaches in adults with chronic migraine** The Trust supports this policy statement and applications will be submitted via BlueTeq. **VIII. Botulinum toxin A for hyperhidrosis** The Trust acknowledges this policy statement and will follow the IFR process if an individual patient demonstrates exceptional clinical circumstances. **IX. Pharmalgen for the treatment of IgE-medicated bee and wasp venom allergy** The Trust supports this policy statement and notes treatment is hospital only. **X. Topical hydrocortisone cream OR ointment** The Trust supports this policy statement and does not have hydrocortisone 2.5% on the formulary. **XI. Freestyle Libre®** The Trust acknowledges the initiation and prescribing transfer agreements for use in paediatric patients. Dr Marr is raising the workload/resource issues around the implementation and ongoing monitoring required for Freestyle Libre® at divisional level. Once a proposal is reached it will be discussed with the CCG. The Trust is still awaiting the final criteria and paperwork from SWL CCG's, but	**AL**

	similar issues will need to be addressed.	
	g) Shared Care Prescribing Guidelines Awaiting response from the gastroenterologists. If they support the document and it is approved at SWL the Trust will support this shared care document	**AL**
12.	**Any Other Business**	
	Dr Shephard and Sarah Taylor have given apologies for the next meeting so all members will be asked for their availability to confirm the committee will be quorate.	**KGA**
13.	**Date of Next Meeting:**	
	Wednesday 15th August 2018, 12:30-14:00. Nightingale Room, Epsom	