NHS
Somerset
Clinical Commissioning Group

Minutes of the **Somerset Prescribing Forum** held in **Meeting Room 2, Wynford House, Lufton Way, Yeovil, Somerset**, on **Wednesday, 8th May 2013**

Present:	Jon Beard	Chief Pharmacist, Taunton & Somerset NHS Foundation Trust	JB
	Andrew Brown	Head of Medicines Management, Somerset Partnership NHS Foundation Trust	AB
	Dr Orla Dunn	Consultant, Public Health, Somerset County Council	OD
	Dr Steve Edgar	GP, Somerset Local Medical Committee representative	SE
	Steve Du Bois	Medicines Manager, NHS Somerset CCG	SDB
	Shaun Green	Associate Director, Head of Medicines Management, NHS Somerset CCG	SG
	Gordon Jackson	Patient Representative	GJ
	Dr Sally Knights	Chair, Drug & Therapeutics Committee, Yeovil District Hospital	SK
	Dr Gerrit Lemmons	Consultant Paediatric Psychiatrist, Somerset Partnership NHS Foundation Trust	GL
	Jean Perry	Commissioning Manager, NHS Somerset CCG	JP
	Dr Iain Phillips	GP Delegate (South Somerset Healthcare Federation), NHS Somerset CCG	GS
	Dr Geoff Sharp (Chair)	GP Delegate (Central Mendip Federation), NHS Somerset CCG	GS
	Martin Taylor	Development Pharmacist, Somerset Local Pharmaceutical Committee	MT
In attendance:	Shelley Hodder	Administrator, Medicines Management, NHS Somerset CCG	SH
Apologies:	Dr Clare Barlow	Chair, Drug & Therapeutics Committee, Taunton & Somerset NHS Foundation Trust	CB
	Dr Rosie Benneyworth	GP Delegate (Taunton Deane Federation), NHS Somerset CCG	RB
	Dr Ulrike Harrower	Consultant, Public Health, Somerset County Council	UH
	Liz Harewood	Medicines Manager, NHS Somerset CCG	LH
	John Martin	Chief Pharmacist, Yeovil NHS Foundation Trust	JM
	Stephanie Wadham	Medicines Information / Formulary Senior Pharmacist, Yeovil NHS Foundation Trust	SW

1 INTRODUCTION

1.1 GS welcomed all to the first meeting of the Somerset Prescribing Forum now that the NHS reforms had taken effect and responsibility had officially been passed to the NHS Somerset Clinical Commissioning Group. SDB would be taking over from LH as secretary to the Forum. Dr Orla Dunn was welcomed and would be attending the Forum as the Local Authority Public Health representative in place of UH for future meetings.

1.2 Dr Ulrike Harrower was thanked for her contribution to the Forum.

1.3 Liz Harewood is leaving the CCG at the end of May and was thanked for her significant contribution to the Somerset Prescribing Forum.

1.4 Dr Gerrit Lemmons was welcomed. Dr Lemmons was in attendance for presenting Item 7.9 on the agenda: Somerset Partnership Melatonin guidelines. (NB: Dr Lemmons was only present for the item he was presenting.)

2 APOLOGIES

2.1 Apologies were received from:

- Dr Clare Barlow, Chair, Drug & Therapeutics Committee, Taunton & Somerset NHS Foundation Trust
- Dr Rosie Benneyworth, GP Delegate (Taunton Deane Federation), NHS Somerset CCG
- Liz Harewood, Medicines Manager, NHS Somerset CCG
- John Martin, Chief Pharmacist, Yeovil NHS Foundation Trust
- Stephanie Wadham, Medicines Information / Formulary Senior Pharmacist, Yeovil NHS Foundation Trust

3 DECLARATIONS OF INTEREST

3.1 There was a brief discussion on the Declarations of Interest.

3.2 Members were asked to notify the Prescribing Forum secretary (SDB) of any standing declarations of interest which could be held on record.

Action: All

3.3 The CCG corporate governance would be consulted on the level of detail needed for the declarations.

4 MINUTES OF MEETING HELD ON 13 March 2013

4.1 The minutes were accepted as an accurate record of the meeting

5 MATTERS ARISING

5.1 Matters arising otherwise not on the agenda:

1. **Ranibizumab injection (*Lucentis*®▼) for diabetic macular oedema (DMO)** –the CCG asked acute Trusts for declarations on implementation of NICE TA 274 (Feb-13). TST stated it was non-compliant as a result of the lack of clinical capacity.

6 TERMS OF REFERENCE

6.1 Draft Terms of Reference we presented to the Forum amended in accordance with the discussions at the March meeting. Wording for the key areas for amended were agreed:

1. Paragraph 5.5 regarding appeals against SPF decisions
2. Section 7 – regarding membership. The Forum agreed that at least one GP delegate from the CCG Clinical Operations Group (COG) should be present at meetings, ideally two.
3. Paragraphs 8.1 and 8.3 regarding scheduling of meetings and quorum.

7 D&TC DECISIONS

7.1 **TST**

- Anticholinergics – management of urinary incontinence in women:
  - First-line options for pharmacological treatment were agreed as instant release (IR) tolterodine and IR oxybutynin. Modified release (MR) trospium (*Regurin XL*®) and solifenacin (*Vesicare*®)are second-line.
  - The β3 adrenoceptor agonist mirabegron (*Betmiga*®▼) was approved as a third-line option in anticipation of the forthcoming NICE CG recommendations.
- Metolazone (no longer marketed in the UK): a definite role for the drug remains, therefore, metolozone was agreed as an 'amber' drug after UK licensed and marketed products were found to be ineffective or inappropriate.
- Nicotinic acid MR: the product had been withdrawn from the UK market. Further discussion was deferred to next meeting.
- Bupivacaine epidural bags – TEVA bags would no longer be used after current stock had been exhaustive for safety reasons.

7.2 **YDH**

- Lisdexamfetamine (*Elvanse*®▼)for ADHD as a second-line option - the decision was deferred until after publication of the NICE ESNM and after the Scottish Medicine Consortium decision on the drug.
- *Plasma-Lyte 148*® - approved as a replacement for Hartmann's solution subject to a review if the price rises after the current price-matching period ends.
- Aclidinium inhaler▼ – approved following the CCG approval as 'green' and inclusion on the primary care prescribing formulary
- Alemtuzumab – approved for the treatment of B-cell chronic lymphocytic leukaemia (B-CLL) where fludarabine combination chemotherapy is not appropriate.
- Ipilmumab▼ and vemurafenib▼ – both medicines were approved for use in accordance with NICE TA 268 (Dec-12) and TA 269 (Dec-12) respectively for adding to the YDH formulary.
- Co-trimoxazole – approved for the treatment of cellulitis (third-line) as a 'red' drug in accordance of the recommendations of the TST Antimicrobial Prescribing Group (TSAPG) and the PAMM.

8 NICE

8.1 A summary of the NICE guidance published in March and April was presented to the Forum for information.

8.2 NICE TA 277 (Methylnaltrexone for treating opioid-induced bowel dysfunction) had been terminated. Methylnaltrexone (*Relistor*®) had previously been approved by the Forum as a "green" drug. The Forum would revisit this decision in light of the terminated appraisal.

Action: SDB

8.3 NICE IPG 452 recommends that occipital nerve stimulation (ONS) for intractable chronic migraine should only be used with special arrangements for clinical governance, consent, and audit or research. The CCG asked Trusts to identify patients that had received this intervention or would be suitable for ONS.

Action: CB & SK

8.4 **NICE CG 157 Hyperphosphataemia in chronic kidney disease (Mar-13)**

Calcium-based phosphate binders to control serum phosphate are recommended as the first-line option (there are slight variations in recommendations between use in children and young adults and in adults.)

Sevelamer and lanthanum carbonate are second-line options either alone in addition to calcium-based phosphate binders.

Sevelamer and lanthanum are NHS England specialist commissioning drugs, the calcium-based phosphate binders are not.

8.5 **NICE CG 158 Conduct disorder in children and young people (Mar-13)**

The guidance was presented to the group for information. The guidance is most applicable to Somerset Partnership and secondary care paediatricians treating this patient group. The guidance recommends against pharmacological interventions for the routine management of conduct disorder. Methylphenidate or atomoxetine is recommended for patients with ADHD with oppositional defiant disorder or conduct disorder in line with NICE CG 72. Risperidone may be considered for the short-term management of severely aggressive behaviour with conduct disorder where there are problems of explosive anger or severe emotional dysregulation where psychosocial interventions have failed.

8.6 **NICE TA 276 Colistimethate sodium and tobramycin dry powders for inhalation for treating pseudomonas lung infection in cystic fibrosis (Mar-13)**

The guidance was presented to the group for information. Cystic fibrosis treatment and management is via NHS England specialist commissioning.

8.7 **NICE TA 278 Omalizumab for treating severe persistent allergic asthma (review of technology appraisal guidance 133 and 201) (Apr-13)**

Omalizumab (*Xolair*®) has been approved for use in adults and children over 6 years. Funding for treatment is via NHS England Specialist Commissioning and requires the manufacturer to offer the drug at a discount agreed in agreed the patient access scheme.

8.8 **NICE TA 279 Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures (Mar-13)**

The guidance was presented to the group for information. It was noted that the guidance may raise some commissioning issues. SK thought that the treatment would be part of normal practice; SG recommended that TST and YDH representatives raise the item for discussion in their respective Trusts.

Action: CB & SK

8.9 **NICE TA 280 Abatacept for treating rheumatoid arthritis after the failure of conventional disease-modifying anti-rheumatic drugs (rapid review of TA 234) (Apr-13)**

Intravenous abatacept in combination with methotrexate (MTX) had been approved for treatment of RA after failure of conventional DMARDs. SK commented that the 'AMBER' trial had shown that abatacept (*Orencia*®) s/c was non-inferior to i/v. Trusts were advised to sign-up to the agreed patient access scheme.

8.10 **NICE TA 282 Pirfenidone for treating idiopathic pulmonary fibrosis (Apr-13)**

NICE recommendations for pirfenidone (*Esbriet*®▼) require strict criteria to be met before use, with stop criteria, and include the provision of a manufacturer's patient access scheme. The drug is listed as an NHS England Specialist Commissioning funded treatment. Funding for treatment is thought to be by individual funding request to the Wessex area team of NHSE.

8.11 **NHS England Specialist Commissioning of NICE approved drugs**

NHSE Specialist Commissioning have issued a statement that NICE guidance would not be adopted until the end of the NICE 90-day implementation period. This raised questions on how patients could receive treatment for specialist commissioning drugs or interventions in the 90-days between guidance publication and funding by NHSE. The individual funding request route may have to be considered by consultants if they find patients falling into this window.

9 FORMULARY APPLICATIONS

9.1 **Paliperidone▼: maintenance therapy in schizophrenia in adults**

Paliperidone (*Xeplion*®▼), a second-generation antipsychotic depot injection and a metabolite of risperidone, licensed for use in schizophrenia for the management of psychotic or manic symptoms of schizoaffective disorder, is a once a month injection with no cold-chain requirements. The injection was reported to be easier to use and initiate and would be a cost-neutral alternative to the risperidone depot injection in certain circumstances. There was no plan to switch patients already stabilised on ripseridone depot injection to the new product and introduction would be tightly controlled by the Somerset Partnership MCIP. **Approved: RED**. Amber status may be sought in due course once experience with the drug and route had been gained.

9.2 **Rivaroxaban for treating pulmonary embolism (PE) and preventing recurrent venous embolism**

NICE published the final appraisal determination in April 2013 which recommended rivaroxaban as an option for treating PE and preventing deep vein thrombosis and PE in adults. Rivaroxaban was **approved GREEN** on condition no change in the recommendations on publication of the final guidance after the consultation period.

9.3 **Ranibizumab for treating visual impairment caused by macular oedema secondary to retinal vein occlusion (RVO)**

NICE published the final appraisal determination in April 2013 which recommended ranibizumab (*Lucentis*®▼) as an option for treating visual impairment caused by macular oedema following RVO or following branch RVO if photocoagulation is unsuccessful or not suitable because of the extent of macular haemorrhage. A manufacturer's patient access scheme is available.

9.4 The Forum acknowledges there would be capacity issues in Trusts and the CCG and the Trusts needed to discuss addressing these capacity issues. The capacity at TST was reported to be in the retinal assessment rather in the provision of injections. Ranibizumab was **approved RED** on condition no change in the recommendations on publication of the final guidance after the consultation period

9.5 **NICE ESNM 10 - Type 2 diabetes: Lixisenatide (Jan-13)**

Lixisenatide (*Lyxumia*®▼) is a once daily glucagon-like peptide-1 (GLP-1) mimetic for use in combination with basal insulin or oral antidiabetic drugs for treating type-2 diabetes in adults. Lixisenatide had been previously considered by the Forum and was "not recommended" for use in Somerset. The price had now been confirmed and was less than the alternative GLP-1 mimetics, exenatide and liraglutide. Lixisenatide also had the advantage of a once daily dosing similar to liraglutide, as opposed to the twice-daily dosing required for exenatide, which may be an advantage in some patients. **Approved GREEN**.

9.6 Trusts were asked to consider making lixisenatide a first-line choice for new patients on the basis of cost-effectiveness. Switching from the other GLP-1 mimetics to lixisenatide would have to be considered by individual clinicians for appropriateness.

Action: AB, CB & SK

9.7 **NICE ESNM 11 - Acute diarrhoea in adults: Racecadotril (Mar-13)**
NICE ESNM 12 – Acute diarrhoea in children: Racecadotril as an adjunct to oral rehydration (Mar-13)

Racecadotril (*Hidrasec*®) is licensed for the symptomatic treatment of diarrhoea in adults and for the complementary symptomatic treatment of acute diarrhoea in children aged over 3 months together with oral rehydration. Racecadotril was **not recommended** by the committee on the basis of lack of demonstration of clinical and economic benefit over current treatment practice in both patient groups.

9.8 **NICE ESNM 16 – Irritable bowel syndrome with constipation in adults: Linaclotide (Apr-13)**

Linaclotide (*Constella*®) a first-in-class, oral, once-daily guanylate cyclase-C receptor antagonist (GCCA) is licensed for the symptomatic treatment of moderate to severe IBS with constipation (IBS-C) in adults. The available evidence did not identify the place of linaclotide in the management of IBS-C as no head-to-head studies for comparison with current accepted treatments had been published. The Forum would review fully if a formal application for use in Somerset was received but would be **not recommended** in the interim.

9.9 **NICE ESNM 16 – Irritable bowel syndrome with constipation in adults: Linaclotide (Apr-13)**

Linaclotide (*Constella*®) a first-in-class, oral, once-daily guanylate cyclase-C receptor antagonist (GCCA) is licensed for the symptomatic treatment of moderate to severe IBS with constipation (IBS-C) in adults. The available evidence did not identify the place of linaclotide in the management of IBS-C as no head-to-head studies for comparison with current accepted treatments have not been published. The Forum would review fully if a formal application for use in Somerset was received but would be **not recommended** in the interim.

9.10 **NICE ESNM 17 – Partial-onset seizures in epilepsy: Zonisamide as monotherapy (Apr-13)**

The license for zonisamide (*Zonegran*®) had been extended to include monotherapy for treating partial-onset seizures, with or without secondary generalisation, in adults with newly diagnosed epilepsy. Zonisamide was considered to offer an alternative to other anti-epileptic drugs in some patients because of its different mechanism of action, once-daily dosing, and adverse event and interaction profiles (it is thought not to interact through cytochrome P450-mediated mechanisms.) Zonisamide had previously been approved for use in Somerset for adults by the Forum as an adjunctive treatment of partial seizures, with or without secondary generalisation.

9.11 Zonisamide was **approved AMBER** for use a monotherapy in line with the license extension. The Forum expected consultants to fit the drug into the current pathway and use the drug as a 7th or 8th line option.

9.12 **NICE ESNM 18 – Lower urinary tract symptoms secondary to benign prostatic hyperplasia: tadalafil (Apr-13)**

The license for the 5mg once-daily tablet only of tadalafil (*Cialis*®), a reversible phosphdiesterase type 5 inhibitor, had been extended to treatment of signs and symptoms of benign prostatic hyperplasia (BPH) in adult men. Assessing tadalafil's place in therapy for this indication was not possible with currently available evidence. **NOT RECOMMENDED**.

9.13 ESNM 18 stated that prescribing tadalafil solely for the treatment of BPH on the NHS FP10 prescription (i.e. did not meet the 'SLS' criteria for prescribing) did not breach Schedule 2 of the *NHS (General Medical Services contracts) (Prescription of drugs etc) Regulations 2004* was believed to be incorrect and the Department of Health had been asked to raise the issue with NICE and ask that the statement is withdrawn from the ESNM.

9.14 **NICE ESUOM 9 – Fatigue in multiple sclerosis: modafinil (Apr-13)**

The summary of the evidence for the unlicensed indication of modafinil did not find any statistically significant evidence of reduction of symptoms of fatigue in MS. It was noted that the treatment of multiple sclerosis was a NHSE Specialist Commissioning treatment; therefore, requests for this indication should be treated as **RED** by primary care prescribers.

9.15 **NICE ESUOM 10 – Nocturia and nocturnal polyuria in men with lower urinary tract symptoms: oral desmopressin (Apr-13)**

NICE CG97 (Lower urinary tract symptoms. May-10) recommended oral desmopressin as an option in the treatment of nocturnal polyuria (unlicensed indication) based on expert opinion.

The summary of the subsequently available evidence supports the NICE recommendation (NNT = 2), however, it was noted that treatment makes hyponatraemia and water intoxication more likely in instances of inappropriate fluid intake. Clinicians and patients are advised to follow MHRA guidance and the advice on fluid intake in the products Summary of Product Characteristics. **Approved GREEN**.

9.16 **Somerset Partnership NHS Foundation Trust Melatonin Guidelines**

Dr Lemmons presented the case for the use of melatonin by the CAMHS and the proposal for the status of melatonin to be an amber drug with a shared care guideline (to be developed if approved.)

Melatonin is currently not recommended (all indications) for primary care prescribing in Somerset. *Bio-Melatonin*® (instant release form) and *Circadin*® (a modified release product) are the current brands of melatonin used by SomPar to contain the cost-pressure of prescribing. Dr Lemmons and his service recognised that the evidence was not strong but experience had shown that a number of children found the treatment useful in three-monthly blocks of treatment; mainly in individuals with learning difficulties or sensory impairment. Usefulness in certain circumstances is supported by the BNF for

Children (cBNF.)

9.17 The CCG view was that there was a lack of evidence; studies did not reach statistical significance for the benefit of melatonin, therefore, from a commissioning standpoint did not recommend use. However, the CCG did recognise that primary care clinicians have the clinical freedom to take on prescribing if they feel that prescribing is beneficial for an individual.

9.18 TST reported cessation of melatonin treatment for a number paediatric patients after review.

Status remains **NOT RECOMMENDED.**

10 PBR EXCLUDED DRUG MONITORING

10.1 This was a new role for the Forum. A number of papers were presented to the Forum giving details of PBR excluded drug funding and the implications with the division of funding between NHS England and CCGs implemented on 1 April 2013 as part of the NHS reforms.

10.2 The Forum was presented with two MS Excel spreadsheets detailing the split for the reimbursement responsibilities between CCGs and NHSE Specialist Commissioning. The list of PBR excluded drugs that are funded by CCGs includes a number of drugs not approved for use or commissioned in Somerset for example collagenase or sodium oxabate; therefore, use should be preceded by an application for use to through the respective Trust D&TC, the Forum, or via a request for individual funding.

10.3 Acute Trusts had been requested to provide data on PBR excluded drug spend that the CCG was responsible for; YDH had provided data (presented); TST data had not been received at the time of the meeting.

11 DRUG SAFETY

11.1 Tiotropium soft mist inhaler (SMI) cardiovascular safety concerns

Previously raised safety concerns on this particular formulation of tiotropium was supported by a recently published paper (Verhamme *et al.* (2013) *Eur Resp J Express* Published online before print 21 March 2013.) The recent study concluded that tiotropium (*Spiriva*®) SMI (*Respimat*®) was associated with ~30% increase mortality compared to the tiotropium dry-powder inhaler (DPI; *Handihaler*®.) Association was strongest for CV / cerebrovascular death.

11.2 Data was presented to show that use had decreased in Somerset (~800 packs pre month in Jun-11 to ~300 packs a month in Jan-13). Previously the Forum had stopped short of making the tiotropium SMI “non-formulary” and ‘not recommended’, however, alternatives now existed. The Forum agreed that risk outweighed the benefit and the product was to be removed from the Primary Care Prescribing Formulary and would be **NOT RECOMMENDED** but the members recognised that clinical freedom to prescribe should be

respected where there was no appropriate alternative.

11.3 **MHRA Drug Safety Update March 2013 (Volume 6, Issue 8)**

The update was presented to the group for information. Of particular note were:

- Dabigatran (*Pradaxa*®)– NOACs were not licensed for use with prosthetic heart halves and use was associated with negative outcomes. Dabigatran is now contraindicated for this use.
- Aqueous cream may cause skin irritation possible caused by the excipient sodium lauryl sulphate in the formulation.
- Botulinum roxin type B (*Neurobloc*®) – serious reactions associated with off-label use, therefore, prescribers are advised to adhere to licensed uses only.

11.4 **MHRA Drug Safety Update April 2013 (Volume 6, Issue 9)**

The update was presented to the group for information. Of particular note were:

- Insulin degludec (*Tresiba*®▼) –marketing in two strengths raised concerns over medication errors.
- Cilostazol (*Pletal*®) – risks of CV and bleeding events, therefore indication restricted to second-line treatment and contra-indicated with some CV conditions and medicines. Somerset use of the drug was noted as being low.
- Strontium ranelate (*Protelos*®) – risk of serious cardiac disorders. Use restricted, and new contraindications and warnings have been added. Somerset use has been declining as concerns have grown.

11.5 **Atrial Fibrillation Oral Anticoagulation Card for non-vitamin K anticoagulants**

The Forum discussed the card and associated guidance produced jointly by the European Society of Cardiology and European Heart Rhythm Association. It was felt that the card was not applicable for all situations where the new oral anticoagulants (NOACs) were prescribed but it was thought that the card may be useful for some patients. Therefore, the Forum agreed that some prescribers may find it useful when prescribing NOACs for some patients. The PDF of the card would be uploaded on the Medicines Management webpages.

Action: SDB

11.6 Trust representatives were asked to take the card and the guidance back to their respective Trusts for discussion.

Action: AB, CB, & SK

12 CANCER DRUG FUND

12.1 The letter of 14 April 2013 from Kate Caston, Head of Specialised Services, NHS England to NHSE Area Team Directors (Ref: KC/SL/14413) regarding review of the CDF drugs list was shared with the group. The letter detailed the changes in the regional CDF drugs lists and subsequent merger into a single national list.

13 ANY OTHER BUSINESS

13.1 No other business was raised.

DATES OF NEXT MEETING:

Wednesday 10 July 2013

Meeting ended.

FORTHCOMING MEETINGS:

All meetings to be held at the offices of NHS Somerset CCG at Wynford House, Yeovil between 2.30pm and 5pm:

- Wednesday 10 July 2013
- Wednesday 18 September 2013
- Wednesday 13 November 2013

SCHEDULE OF ACTIONS

NO.	SUBJECT	OUTSTANDING RESPONSIBILITY	ACTION LEAD
ACTIONS ARISING FROM THE MEETING HELD ON WEDNESDAY 8 MAY 2013			
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