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DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on Tuesday 10 June 2014

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Silk Garments (e.g.DermaSilk, DreamSkin, Skinnies Silk)	BROWN Specialist Initiation and following assessment of efficacy
Elastolabo Gel	BLACK
Linaclotide	RED (reclassified from Black)
Virulite Light Therapy	BLACK
Silica gels/sheets	BLACK
Pivmecillinam	GREEN 2nd line for lower UTIs that is resistant to trimethoprim, nitrofurantoin and amoxicillin (MSU confirmed)
Sitagliptin	GREEN 1st line glipitin choice
Linagliptin	GREEN alternative 1st line gliptin for patients with renal and hepatic impairment
Saxagliptin	GREEN (Preferred 1st line gliptin is sitagliptin or linagliptin for patients with renal and hepatic impairment)
Alogliptin	GREEN (Preferred 1st line gliptin is sitagliptin (or linagliptin for patients with renal and hepatic impairment)
Vildagliptin	GREEN (Preferred 1st line gliptin is sitagliptin (or linagliptin for patients with renal and hepatic impairment)
Alemtuzumab	RED as per NICE TA 312
Ustekinumab	BLACK as per NICE TA 313, for the treatment of psoriatic arthritis

Clinical Guidelines

Antimicrobial Treatment Guideline
Diagnosis and Management of Lower Urinary-Tract Infections Guideline
Management of Clostridium difficile Infection in Primary Care Guideline
Use of Compression Hosiery in Primary Care Guideline
Management of Type 2 Diabetes Guideline
Infant Feeding Guideline

Shared Care Guideline

Drugs Used in the Management of ADHD in Adults and Children (joint shared care)

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Present:	
Southern Derbyshire CCG	
Dr A Mott	GP (Chair)
Mr S Dhadli	Specialist Commissioning Pharmacist (Secretary)
Mr D Harvey	Finance Officer
Mr S Hulme	Director of Medicines Management
Dr M Watkins	GP
North Derbyshire CCG	
Dr C Emslie	GP
Mrs K Needham	Head of Medicines Management North (also representing Hardwick CCG)
Hardwick CCG	
Dr T Parkin	GP
Derbyshire County Council	
Mrs S Qureshi	NICE Audit Pharmacist
Derby Hospitals NHS Foundation Trust	
Dr W Goddard	Chair – Drugs and Therapeutic Committee
Mr C Newman	Chief Pharmacist
Derbyshire Healthcare NHS Foundation Trust	
Dr S Taylor	Chair – Drugs and Therapeutic Committee
Chesterfield Royal Hospital NHS Foundation Trust	
Mr M Shepherd	Chief Pharmacist
Derbyshire Community Health Services NHS Trust	
Mr M Steward	Chief Pharmacist

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Item		Action
1.	**APOLOGIES**	
	Dr D Fitzsimons, Dr M Henn, Mrs L Hunter and Dr C Shearer.	
2.	**DECLARATIONS OF CONFLICT OF INTEREST**	
	No declarations of conflict of interest were made.	
3.	**DECLARATIONS OF ANY OTHER BUSINESS**	
	• Vaginal Dilators by RDH	
4.	**MINUTES OF JAPC MEETING HELD ON 13 MAY 2014**	
	The minutes of the meeting held on 13 May 2014 were agreed as a correct record after an amendment to the list of attendees to read Mr M Steward – Chief Pharmacist.	
5.	**MATTERS ARISING**	
a.	**Annualised ADR Rates for NOACs** Mr Dhadli commented that JAPC had previously discussed the number of adverse drug reactions (ADRs) and fatal ADRs through data from the MHRA for the NOACs and warfarin. Mr Dhadli reported that the MRHA had been contacted and confirmation received that annualised ADRs could be supplied and these would be brought to a future JAPC meeting.	**SD**
b.	**Anti-epileptics Update** Mr Hulme gave feedback on recent MHRA advice where prescribing by brand or manufacturer was recommended for class 1 of antiepileptic drugs (AEDs). Mr Hulme stated every effort had been made to ensure that practice records were appropriately updated and that the drugs were accurately recorded indicating a brand or manufacturer. The risk of the patient not receiving continued supply of the same brand was identified at being at the interface when patients moved into a secondary care setting. To overcome this patients would need to be reminded to take their medicines with them if they went into secondary care. A risk had been highlighted concerning the swapping to a different brand or generic in hospital without the knowledge of the patient or prescriber and also not identified on discharge. Mrs Needham commented that it may be advantageous to establish how many patients would be affected in order to establish the extent of the potential problem. JAPC noted that the issue of implementing this MHRA advice was a national and local issue. The heads of medicines management agreed to feedback to the MHRA via regional networks.	**SH/KN**
c.	**Vacuum Pumps** Dr Goddard queried a previous decision recommending vacuum pumps to be prescribed by secondary care only. Mr Newman advised that feedback had been obtained from the specialist clinic to outline the pathway and the governance arrangements. Dr Goddard stated that the service was run by the urology continence nurse specialists and, following a trial of two main products, a recommendation would be made as to which product should be provided by GPs. Dr Mott requested RDH to present a clear patient pathway to JAPC.	**RDH**

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6.	**NEW DRUG ASSESSMENTS/TRAFFIC LIGHT ADDITIONS**	
a.	**Silk Garments (e.g. DermaSilk)** Mr Dhadli reported that silk garments such as DermaSilk and DreamSkin, for the treatment of atopic eczema, were listed on other CCGs formularies as not recommended. They are listed as an appliance in part IXA of the drug tariff and relatively expensive. Mr Dhadli highlighted the lack of high level evidence in the literature for their use and potential growth for prescribing if not carefully managed. It was noted that Nottingham were recruiting 300 children to a £1m CLOTHES trial run by the National Institute for Health Research to test for efficacy, although results to indicate effectiveness or not would not be available until 2016. Feedback had been received from the Chesterfield Royal Hospital dermatologists that it had been found to be useful with children. In addition the Royal Derby Hospital dermatologists had case studies of their use in very severe eczema in two patients aged 40 and 5 years. JAPC agreed to restrict their use following specialist assessment in order to identify those patients most likely to benefit. **Agreed:** Silk Garments **(**DermaSilk, DreamSkin and Skinnies) classified as a **BROWN** specialist initiation medical device and assessment of efficacy.	**SD**
b.	**Elastolabo Gel** Mr Dhadli advised JAPC that elastolabo gel was the only product indicated for antenatal perineal massage to be used by pregnant women from 32 weeks of pregnancy. It was listed as an appliance in part IXa of the drug tariff with price of £1458 with a typical treatment requiring one or two tubes. The evidence for perineal massage for the reduction of perineal trauma comes from a Cochrane review. The review concluded that the act of perineal massage was clinically efficacious due to the reduced need for suturing and reduction in episiotomy and in pain. The evidence of using elastolabo with perineal massage was however supported by a poor study. Mr Dhadli reported that the study of 118 patients was open label, single arm study with no control. It lacked a uniformly accepted reference comparing data to national and regional data. **Agreed:** Elastolabo gel classified as **BLACK.**	**SD**
c.	**Linaclotide** Dr Goddard advised that linaclotide had been considered by the RDH Drugs and Therapeutic Committee and was licensed for the symptomatic treatment of moderate to severe irritable bowel syndrome with constipation (IBS-C) in adults where patients had been unresponsive to a variety of fibre treatments, laxatives and tricyclic antidepressants. A patient pathway had been developed and evidence came from two phase 3 double blind placebo controlled RCTs of patients with IBS with constipation. During discussion Mr Dhadli referred to the two trials and highlighted the following which was considered when JAPC had originally classified this as black in May 2013: • In both trials rescue medication was allowed for severe constipation.	

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	Trial 1 also allowed patients on a stable, continuous regimen of fibre bulk laxatives, stool softeners or probiotics during the 30 days before screening visit to continue provided they maintained a stable dosage. • Several authors were employees or pain consultants of the company which supported the trials both financially and editorially. • Primary outcomes measured at 12 weeks and 26 weeks and deemed relatively short. • The EMA was awaiting the final results of long term safety data. • Linaclotide had not been assessed against an active comparator. • Effectiveness from these trials was similar to those seen with laxative use in patients with chronic constipation. • There had been a large placebo response. JAPC noted that MTRAC had suggested use in a limited number of patients when all other treatment options had been ineffective or contraindicated. The DTB also noted its limited role where all other treatment options have been ineffective or contraindicated. JAPC considered the pathway presented by RDH and several changes were proposed that would ensure adequate monitoring of the treatment. As discussions continued about the therapeutics of how the drug works, together with lack of long term data and experience, it was agreed to classify as red. Dr Goddard agreed to re-submit the pathway to JAPC subject to some minor changes and feedback of efficacy and safety in the near future **Agreed:** Linaclotide classified as a **RED** drug. **Action:** Long term safety data would be obtained by the use of the drug in clinic and this would be presented to JAPC in a year's time.	**SD** **WG**
d.	**<u>Virulite Light Therapy</u>** Mr Dhadli reported Virulite is a prescribeable appliance listed in the drug tariff. Light therapy for cold sores (herpes labialis) was delivered by means of a laser light given for 3 minutes twice daily over two days. Evidence supporting the product comes from a randomised prospective double-blind double-dummy study to comparing it to aciclovir. The study was small and the majority of patients started treatment between 18-36 hours at onset of symptoms unlike how acyclovir is currently used (i.e. Prodromal phase) **Agreed:** Virulite Light Therapy classified as **BLACK.**	**SD**
e.	**<u>Silica gels and Sheets</u>** Mr Dhadli reported that silica gel and sheets are used for the prevention and treatment of hypertrophic and keloid scars. Evidence presented was derived from a Cochrane review, September 2013, which had indicated that there was some benefit in the use of silicone gel and sheets for the prevention for abnormal scarring in high risk patients but the evidence was weak and subject to bias. Similarly there was also poor quality of research and bias concerning	

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	use as a treatment for hypertrophic and keloid scarring. It was unclear from JAPC discussions what was driving the current level of prescribing. There was also some consideration for the use of silica gel and sheets in the Cosmetic policy. **Agreed:** Silica gels classified as **BLACK** drugs.	**SD**
7.	**CLINICAL GUIDELINES**	
a.	**<u>Antimicrobial Treatment Guidance</u>** Mr Dhadli highlighted the changes made by Dr Diane Harris, Specialist Antimicrobial Pharmacist, to the antimicrobial treatment guidelines: • Amoxicillin – Increased dose for children aged 12 to 18 years to 500mg-1g TDS (for severe infections) which was reflected in the British National Formulary for Children. • Pivmecillinam had been added as a 2nd line option for lower UTIs. The current UTI was limited to trimethoprim and nitrofurantoin and there was advice to avoid broad spectrum antibiotics (C Diff/MRSA/resistant UTIs) and also problems of renal impairment with trimethoprim. • Nitrofurantoin had been changed from immediate release 50-100mg QDS to 100mg BD modified release formulation as per HPA. **Action:** Sensitivity reporting for the use of pivmecillinam would be checked with Dr Harris and report findings at next JAPC meeting. **Agreed:** Pivmecillinam classified as a **GREEN** drug 2nd line for lower UTI (MSU confirmed).	**SD** **SD**
b.	**<u>Diagnosis and Management of Lower Urinary-Tract Infections (UTI)</u>** Mr Dhadli highlighted the changes made by Dr Diane Harris to the diagnosis and management of lower UTI guidance: • The dose of nitrofurantoin had been amended to 100mg m/r bd for uncomplicated UTIs and UTIs in pregnancy. • Details regarding Amoxicillin and Pivmecillinam had been added in accordance with the amended Antimicrobial Treatment Guidelines. **Agreed:** JAPC ratified the amended guidelines for the diagnosis and management of lower UTI.	**SD**
c.	**<u>Management of Clostridium difficile infection (CDI) in Primary Care</u>** Mr Dhadli highlighted the changes made by Dr Diane Harris to the management of CDI in primary care: • Guidance was made clearer stating vancomycin was the preferred treatment in recurrence of CDI. • Details of obtaining vancomycin. • Details included regarding the preparation of an oral solution. It was agreed that the reference to the preparation of an oral solution of vancomycin be omitted from the guidance. **Agreed:** JAPC ratified the management of Clostridium difficile infection in primary care guidance with the agreed amendment.	**SD** **SD**

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d.	**Compression Hosiery** Mr Dhadli stated that JAPC had previously requested the Guideline Group to produce a guideline for the appropriate use of compression hosiery in primary care. **Agreed:** JAPC ratified the guideline for the use of compression hosiery.	**SD**
e.	**Management of Type 2 Diabetes** Mrs Qureshi advised that the updated version of the diabetes guideline had been discussed in depth by JAPC at its previous meeting and it had been agreed to bring back Dr Game, RDH Consultant Diabetologist, views regarding classification of gliptins. Accordingly communication had now been received and Dr Game agreed with Dr Robinson's view of two gliptins to be classified as green first line. Dr Game had also agreed with a preferred choice of gliptins as sitagliptin first line and linagliptin for patients with renal and hepatic disease. Mrs Qureshi added other minor amendments had been made to the guidance, including traffic light classification of pioglitazone and GLP1s to be in line with the discussions at the previous JAPC meeting. Also the algorithm had been amended to merge the two middle boxes into one and to reverse the order of gliptins and GLP1s in the box. **Agreed:** Sitagliptin classified as **GREEN 1st line choice** drug. **Agreed**: Linagliptin classified as **GREEN alternative 1st line** drug for patients with renal and hepatic impairment. **Agreed:** Saxagliptin, alogliptin and vildagliptin classified as **GREEN** drugs but it was highlighted that sitagliptin and linagliptin are the preferred choices. **Agreed:** JAPC ratified the Management of Type 2 Diabetes Guidelines	**SD** **SD** **SD** **SD**
f.	**Infant Feeding Guidelines** Mr Dhadli advised that the existing guidance had been updated after consultation with dieticians and paediatricians across Derbyshire and highlighted the main changes: • Removal of the phrase 'In North Derbyshire, GPs may decide to diagnose and manage simple cow's milk protein intolerance as per this guide and Chesterfield Royal Hospital's "Infant Formula Ordering Policy" available on the trust intranet' from all sections. • Addition of 'All suspected cases of cow's milk protein intolerance should be referred via a paediatrician for confirmation of diagnosis and a full dietary assessment.' • Addition of 'Secondary lactose intolerance in infants usually lasts 6-8 weeks but may last as long as 3-6 months.' • Addition of 'Only children with specific rare medical conditions require a prescribed soya formula after 1 year of age.' • Addition of additional references.	

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	During discussion Dr Watkins queried the reference in the section 'policy at Chesterfield Royal Hospital' for premature and low birth weight infants' concerning the use of Nutriprem 2 200ml ready to feed cartons. Dr Mott stated that he was involved in some work within the CCG related to this topic and would look into this. Dr Parkin highlighted the lack of a time period in the section concerning approximate quantities to be supplied and Mr Dhadli would contact the author to ensure that this was included. Dr Mott referred to the inclusion of 'All suspected cases of cow's milk protein intolerance should be referred via a paediatrician for confirmation of diagnosis and a full dietary assessment' and suggested that this be changed to 'All suspected cases should be seen by a paediatric dietitian'. This was agreed. **Agreed:** JAPC ratified the Infant Feeding Guidelines with the agreed amendments.	**AM** **SD** **SD**
8.	**SHARED CARE GUIDELINE**	
	Attention Deficit Hyperactive Disorder (ADHD) Shared Care JAPC noted that this is now a joint shared care agreement for adults and children. Dr Taylor referred JAPC to the changes in the shared care agreement: dosing of dexamfetamine in line with BNFc the monitoring of children to be done by specialists and clarity on the adult monitoring for GPs. Derbyshire Healthcare Foundation Trust wanted JAPC to note that it would prefer lisdexamfetamine 2nd line ahead of atomextine. This was noted but JAPC agreed not to revisit this recent decision. Mrs Needham requested that monitoring requirements be included in the GP responsibilities section. Mr Dhadli stated that documented GP monitoring responsibilities have not always been consistent and suggested that all shared cares should cross reference from GP section to the monitoring requirements further in the document **Agreed:** JAPC ratified the shared care guidelines for drugs used in the management of ADHD in children and adults subject to the suggested changes.	**SD**
9	**MONTHLY HORIZON SCAN**	
	Mr Dhadli advised JAPC of the following new drug launches, new drug formulations and drug discontinuations: Brimonidone (Mirvaso) – Already classified as a red drug. Budesonide + formoterol (DuoResp Spiromex) – To be left unclassified (budesonide/formoterol) – To be left unclassified. Human normal immunoglobulin (HyQvia) – Already classified as a red drug.	
10.	**MISCELLANEOUS**	
a.	**Controlled Drugs** Mr Dhadli advised JAPC that the Parliamentary Order 2014 under the 1971 Act and the 2001 Regulations now controlled the following drugs: • The NBOMe compounds, via generic definition, as Class A drugs. • The Benzofuran compounds, via generic definition, as Class B drugs. • Lisdexamphetamine as a Class B drug. • Tramadol as a Class C drug • Zopiclone and zaleplon as Class C drugs	

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	Regulation comes into force on 10 June 2014. This was tabled to inform providers and GPs implications for the writing of prescriptions, storage, emergency supply and destruction of these controlled drugs	
b.	**Excess Treatment Costs (ETCs) – SANAD II** Mr Dhadli reported that there were two RCTs running in parallel which had two treatment arms for the use of levetiracetam and zonisamide in epilepsy. The CCGs were being requested to cover the ETCs for the follow on prescriptions. The anticipated costs per CCG was anticipated to be around £20,292 over the duration of the trial based on eight children per year being recruited, with four in Arm A and four in Arm B, for the full 5.5 years of the trial. Mr Dhadli advised that there would be no conflict with CCG priorities but there could be with NICE Clinical Guideline CG 137 on epilepsy. The financial risk was small.	
11.	**JAPC BULLETIN**	
	Mr Dhadli highlighted amendments to the bulletin to include, that the cellulitis pathway had been updated to include North Derbyshire and Hardwick CCGs and under midazolam that the strengths differed between the two formulations. The JAPC bulletin was ratified by JAPC.	
12.	**MHRA DRUG SAFETY UPDATE**	
	The MHRA Drug Safety Update for May 2014 was noted. Mr Dhadli highlighted the following: • Domperidone was associated with a small increased risk of serious cardiac side effects. Its use was now restricted to the relief of nausea and vomiting and the dosage and duration of use had been reduced. It should no longer be used for the treatment of bloating and heartburn. Dr Goddard was reminded to table a position statement the next JAPC meeting similar to the metoclopramide statement on gastroparesis. • Voriconazole was noted as a high cost drug normally for secondary care prescribing. • Adrenaline auto injector advice for patients at risk of anaphylaxis. People who had been prescribed an adrenaline auto-injector are now recommended to carry two with them at all times for emergency. It was agreed that this advice should be highlighted in the bulletin. • The benefits and risks of statins article highlighted that larger studies looked at efficacy primarily as opposed to safety. The side effects were generally mild and not serious. Myopathy was dose dependent and the benefits outweighing the risks in most patients. • Reminder of the risk of impaired driving ability due to drowsiness the next day after taking zolpidem tartrate for insomnia. A note to be included into the local formulary.	**WG** **SD**
13.	**NICE SUMMARY**	
	Mrs Qureshi informed JAPC of the comments for the CCGs which had been made for the following NICE guidance issued in May. TA312 Alemtuzumab for relapsing –remitting multiple sclerosis. Alemtuzumab was recommended within its marketing authorisation for treating adults with active relapsing-remitting multiple sclerosis. NICE had indicated that this would not have any impact on Payment by Results. Alemtuzumab classified as a **RED** drug.	**SD**

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	TA 313 Ustekinumab for psoriatic arthritis. Ustekinumab was not recommended within its marketing authorisation for treating active psoriatic arthritis alone or in combination with methotrexate in adults when the response to previous DMARD therapy had been inadequate. NICE had indicated that this would not impact on Payment by Results and was unlikely to have a significant cost impact. Ustekinumab had been recommended by NICE for the treatment of plaque psoriaisis in adults. Ustekinumab classified as a **BLACK** drug for this indication.	**SD**
14.	**TRAFFIC LIGHTS – ANY CHANGES?**	
	Classifications Silk Garments (e.g. DermaSilk) – BROWN Specialist Initiation and assessment Elastolabo - BLACK Linaclotide – RED Virulite Light Therapy – BLACK Silica Gels/sheets – BLACK Pivmecillinam – GREEN 2nd line treatment for UTIs that is resistant to trimethoprim, nitrofurantoin and amoxicillin (MSU confirmed). Sitagliptin – GREEN preferred gliptin 1st line gliptin choice Linagliptin – GREEN alternative gliptin 1st line gliptin choice for patients with renal and hepatic impairment Saxagliptin, alogliptin and vildagliptin – GREEN (not a preferred 1st or second line gliptin see diabetes guideline) Alemtuzumab – RED as per NICE TA 312 Ustekinumab – BLACK for the treatment of psoriatic arthritis as per NICE TA313	
15.	**JAPC ACTION SUMMARY**	
	The action summary was noted by JAPC and amendments made: Shared Care Disulfiram and Acamprosate – Dr Taylor reported that this would be considered by DHcFT DTC and would be brought to the July JAPC meeting. Actinic Keratosis – To be brought to the July JAPC meeting. Lixisenatide – To be brought to the October JAPC meeting. Domperidone and gastroparesis – To be brought to the July JAPC meeting. NOACs Gaps in Local Guidelines - To be brought to the July JAPC meeting.	**ST** **SD** **SD** **SD** **SD**
16.	**GUIDELINE GROUP ACTION TRACKER**	
	Mr Dhadli stated that viridal duo had now been approved as an alternative to caverject. The Guideline Group action tracker was ratified by JAPC.	**SD**
17.	**MINUTES OF OTHER PRESCRIBING GROUPS**	
	• Derby Hospitals NHS Foundation Trust Drugs and Therapeutic Committee 15.4.14 • Derbyshire Healthcare Foundation Trust Drugs and Therapeutic Committee 24.4.14 • Burton Hospital Foundation Trust Drugs and Therapeutic Committee 12.5.14	

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	• Sheffield Area Prescribing Committee 15.4.14 • Chesterfield Royal Hospital Drugs and Therapeutic Committee 20.3.14 Mr Dhadli highlighted that Sheffield APC had classified Omacor as black although JAPC had decided to classify this as a brown drug. Homecare could also have an impact on the high cost drugs budget although this was acknowledged to be a national issue.	
18.	**ANY OTHER BUSINESS**	
a.	**Vaginal Dilators** Mr Newman reported that JAPC had classified vaginal dilators as red at the meeting in January and work had been undertaken in RDH to establish which specialty had recommended their use and who had prescribed them. A new pathway had been developed and was being introduced although the CCG had submitted an official contract deviation request. Mr Newman added that it would be necessary in future to allow sufficient time for the implementation of new products. Dr Mott commented that a certain amount of flexibility should be given if difficulties with implementation were anticipated and that it would be important to ensure that relevant messages were conveyed to primary care in cases where a red classification had been given.	
b.	**JAPC Representation** Dr Mott stated that Healthwatch Derbyshire would no longer be attending the meetings of JAPC and consequently there would be a lack of lay representation which was recommended in the JAPC terms of reference. It was agreed that lay representation on JAPC should be further discussed at the July meeting. Dr Mott also highlighted the lack of representation on JAPC from the City and County Public Health directorates. This was particularly important as public health advice would be necessary with the decision making process concerning high cost drugs and whether this input could be given at JAPC meetings or via another forum would need to be agreed. In addition Public Health now commissioned services such as sexual health and smoking cessation which impacted on primary care. There were ongoing discussions about the involvement of public health with JAPC. Dr Mott added that representation from Public Health England on JAPC would also be addressed.	**SD**
19.	**DATE OF NEXT MEETING**	
	Tuesday, 8 July 2014 at 1.30pm in the Post Mill Centre, South Normanton.	