

DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on Tuesday 12 March 2013

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Bromfenac	RED
Loteprednol	RED
Apixaban	RED
Circadin (Metatonin 2mg MR)	BROWN specialist initiation for off licence use in disabled children and CAMHs patients
Rivaroxaban	GREEN specialist initiation for DVT/PE
Ranibizumab	RED
Saxagliptin	BROWN
Co-enzyme Q10	RED for Friedrich's Ataxia (FA)
Co-enzyme Q10	BLACK for all indications except FA

Clinical Guidelines

Rivaroxaban for DVT/PE

Shared Care Guidelines

Melatonin extended to September 2013

Acamprosate in the maintenance of alcohol abstinence

Present:	
NHS Derbyshire County	
Dr J Bell	Assistant Director of Public Health (Chair)
Dr C Emslie	GP – North Derbyshire CCG
Dr D Fitzsimons	GP – North Derbyshire CCG
Mr S Hulme	Head of Prescribing – Southern Derbyshire CCG
Mrs K Needham	Head of Medicines Management North – North Derbyshire CCG
Dr T Parkin	GP – Hardwick CCG
Mrs S Qureshi	NICE Liaison and Audit Pharmacist
Dr I Tooley	GP – Southern Derbyshire CCG
Derbyshire Community Health Services NHS Trust	
Mr M Steward	Head of Medicines Management
NHS Derby City	
Mr S Dhadli	Specialist Commissioning Pharmacist
Derby Hospitals NHS Foundation Trust	
Mr D Anderton	Senior Pharmacist
Dr F Game	Chair – Drugs and Therapeutic Committee
Derbyshire Healthcare NHS Foundation Trust	
Dr S Taylor	Consultant Psychiatrist, Chair – Drugs and Therapeutic Committee
Chesterfield Royal Hospital NHS Foundation Trust	
Mr M Shepherd	Chief Pharmacist
In Attendance:	
Ms S Dakin	Infection Prevention and Control Matron, DCHS
Dr D Harris	Specialist Antimicrobial Pharmacist, Southern Derbyshire CCG
Dr M McKernan	Consultant Haematologist, RDH
Mr A Thorpe	NHS Derby City (minutes)

Item		Action
1.	APOLOGIES	
	Mrs L Hunter and Dr A Mott.	
2.	DECLARATIONS OF CONFLICT OF INTEREST	
	No declarations of interest were made.	
3.	DECLARATIONS OF ANY OTHER BUSINESS	
	<ul style="list-style-type: none"> • Diabetes Guidance 	
4.	MINUTES OF JAPC MEETING HELD ON 12 FEBRUARY 2013	
	<p>The minutes of the meeting held on 12 February 2013 were agreed as a correct record with the following amendments:</p> <p>Summary Points: Cerelle – Amend to: GREEN first line desogestrel preparation. Fosfomycin – BROWN on recommendation of a Consultant Microbiologist Lipid and FH Policies – Amend to ‘JAPC noted the agenda for the working group meeting and evidence papers for review. New Drug Assessments/Formulary Additions – Cerelle classified as a GREEN first line drug desogestrel preparation.</p>	
5.	MATTERS ARISING	
a.	<p><u>Fosfomycin</u> Mr Anderton reported that fosfomycin was to be discussed at the next RDH Drugs and Therapeutic Committee meeting when a decision on its availability at RDH would be made.</p> <p><u>Interactive Traffic Light Database</u> Mr Dhadli stated that there was now a section on the database which would pick up all the horizon scan drugs which had not been yet been fully reviewed by JAPC.</p> <p><u>Vitamin D Deficiency and Treatment with ProD3</u> Mr Shepherd reported that the CRH consultants had indicated that ProD3 was used and there was no evidence to suggest that it was not effective.</p> <p><u>Opioids in Cancer Pain and Non-Cancer Pain</u> Mr Dhadli stated that this had been taken to the Guideline Group and the view had been expressed that it would be difficult to put all four guidelines into one complete document. It had been decided to leave the neuropathic pain as a stand-alone guideline but work would be undertaken on the inclusion of opioids and non-opioids in a joint guideline for GPs to include maximum doses and safety information. Dr Tooley highlighted a possible issue associated with any change in the maximum dose of morphine for use in primary care and a consequent possible increase in referrals to pain clinic by GPs. The revised guideline would be brought to the June JAPC meeting.</p>	SD
6.	NEW DRUG ASSESSMENTS/FORMULARY ADDITIONS	
a.	<p><u>Eye Drops – Bromfenac and Loteprednol</u> Mr Dhadli reported that bromfenac were new eye drops licensed for the treatment of post-treatment inflammation following cataract extraction in adults. The SPC had stated that the treatment should not exceed two weeks as safety information beyond this period was not available and the SMC had not recommended its use.</p>	

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	<p>Bromfenac had been considered by the RDH Drugs and Therapeutic Committee and its proposed use was for post cataract extraction patients who were at high risk of developing central macular oedema (CMO). Its use in primary care was not expected although there had been some prescribing at a cost of £761. Mr Anderton suggested that these prescriptions needed to be checked to ascertain whether these were beyond the two week product licence. In addition, there were other topicals which could be used for this category of patients.</p> <p>Dr Game commented on the specific issues which had been raised about the placement of bromfenac and loteprednol by the RDH Drugs and Therapeutic Committee (DTC) meeting. The DTC had considered that the evidence for loteprednol was limited and a request for clarification on this, and the proposed shared care, had been conveyed to the consultant ophthalmologist for comment but no reply had been received to date. Mr Dhadli added that it would be advantageous for JAPC to share the evidence based reviews which had been discussed by the DTC.</p> <p>Agreed: Bromfenac classified as a RED drug.</p> <p>Agreed: Loteprednol classified as a RED drug.</p>	<p>SD</p> <p>SD</p>
<p>b.</p>	<p><u>Pentoxifylline</u></p> <p>Mr Dhadli reported that a request had been received for use of this drug from a Derbyshire GP and that it was currently listed as a drug of limited clinical value and pentoxifylline had been classified BLACK locally based on the NICE TAG 211 as it was not recommended for the treatment of intermittent claudication with peripheral vascular disease. SIGN guidance and a Cochrane review had indicated that the use of pentoxifylline should be considered in patients with venous leg ulcers as an adjunct when compression was not always possible. The Cochrane review had also stated that there was a cost of £98.09 per QALY gained.</p> <p>During discussion Mr Steward stated that the use of this drug had been discussed with the DCHS Tissue Viability Nurse who had indicated that it could be useful as second line for hard to treat patients who had not responded to a particular course of compression bandaging. Mr Anderton highlighted that its use for venous leg ulcers was an unlicensed indication and Mr Dhadli commented that it would be useful to include in the wound care guideline the cohort of patients who would benefit from the use of this drug. Dr Game advised that a rate of change and healing before discontinuation of the drug would be advantageous to be included in the woundcare formulary.</p> <p>Dr Bell commented that it would be necessary to include a reference to the duration for the period over which compression bandaging had not worked and also duration of pentoxifylline treatment. It was highlighted that an indication of significant improvement would be needed together with the dosage and that it is being used for an unlicensed indication.</p> <p>Dr Tooley commented that clear guidance on the use of pentoxifylline was essential and that it could be a very useful drug for this common, recurring and disabling condition with a potential for significant cost savings. Dr Tooley added that it would</p>	

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	<p>NOAC for patients with AF and one more indication. Dr McKernan to update the guideline. It was agreed to amend CHADS to greater or equal to 1 so this would be compliant with NICE guidance.</p> <p>Action: The revised guideline would be brought back to the June JAPC meeting.</p> <p>b. <u>Rivaroxaban for DVT/PE-RDH</u> Dr McKernan referred to the possibility of a change to the traffic light status of rivaroxaban for the treatment of DVT and prevention of recurrent DVT/PE. This would apply to selected patients at increased thrombotic risk who were very poorly managed on LMWH. These patients were currently managed on treatment dose enoxaparin. This use of rivaroxaban would be initiated in secondary care and GPs would then continue to prescribe it. Dr McKernan highlighted that the cost of rivaroxaban was a quarter of the treatment dose of enoxaparin.</p> <p>Mr Dhadli commented that this was covered by NICE TA 261 and had been agreed as shared care with CRH for drug IV users in the over 18 age group. The duration of treatment for PE was approximately six months and distal DVT approximately three months. The EINSTEIN study had shown non-inferiority to standard therapy of DVT or PE of enoxaparin until INR fell within the therapeutic range and then followed by a Vitamin K antagonist. The evidence of a direct comparison of the NOAC versus LMWH was limited. Mr Dhadli advised that the NICE guidance indicated that rivaroxaban may be less effective when directly compared with low- weight molecular heparin in sub-group analysis and that the manufacturer was undertaking a study as to its long term effectiveness beyond twelve months. In addition rivaroxaban appeared to be less effective than dalteparin the prevention of VTE.</p> <p>Dr McKernan stated that there would be a small group of patients who were on long-term low-molecular weight treatment dose heparin and unable to take Vitamin K antagonists. This small group of patients would be given rivaroxaban together with the occasional patient who was very poorly controlled on warfarin and may have good compliance but who were at high risk of thrombosis. In connection with cancer related clots the recommendation remained to use low-molecular weight heparin but if this could not be used rivaroxaban may be used second line.</p> <p>Agreed: JAPC agreed the use of rivaroxaban for patients on long-term treatment dose enoxaparin or those with very poor control and at high risk of thrombosis.</p> <p>c. <u>Guidance on the Management of Clostridium Difficile</u> Dr Harris reported that she had reviewed again the Clostridium Difficile (C Diff) guidance from December 2012 to February 2013 in consultation with Nicola Smith, Infection Control Nurse at SD CCG and Sue Dakin, Infection Prevention and Control Matron at DCHS. Other Infection Control Nurses have also looked at the guidance and made comments. The guidance had been updated mainly with details regarding the new mandatory 2 stage testing algorithm for Clostridium difficile from the Department of Health which was a more accurate way of testing patients.</p> <p>Dr Harris referred JAPC to the comments which had been received about</p>	<p>MMcK</p> <p>SD</p> <p>SD</p>

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	<p>monitoring in order to determine the severity of disease and response to treatment. Ms Dakin stated that national guidance highlighted the need for a level of daily monitoring. A Root Cause Analysis (RCA) was undertaken on every patient in primary care and the findings from these indicated that a lot of these patients were admitted to acute hospitals with dehydration either from a care home setting or their own home or an exacerbation of their existing medical condition or having the C Diff infection. It would be necessary to clarify the level of monitoring which could be done in the community to try and avoid acute admissions and ensure that the patients had a better recovery.</p> <p>Ms Dakin advised that very small numbers of patients per practice would need to be seen over a six day period and it was therefore proposed that primary care undertook a face to face assessment when they were diagnosed and a medical review done at the same time. An individual assessment would then be carried out to ascertain that the carers and families were able to do a level of monitoring and whether the condition of the patient had improved since commencement of treatment. A further assessment of the patient would then be done by primary care after four to six days to determine whether the treatment had been effective. Close monitoring of the patient was recommended during the first seven days to anticipate any progression from mild disease to more serious disease. The monitoring guidance would be incorporated in the guidance.</p> <p>Mr Hulme gave comments from Dr Mott who was unable to be present at the meeting. Dr Mott considered that the assessment and monitoring of a patient at home was the responsibility of the GP but had concerns about weekends and out of hours. Dr Mott had also queried what would prompt a physical review and that it would be useful to have an explicit list of parameters to enable a GP to make a decision. Dr Harris stated that a reference had been included to ensure that patients and carers understood the importance of monitoring and that signs of deterioration of abdominal tenderness or pain, fever and increasing diarrhoea should be reported to a healthcare professional. Dr Fitzsimons highlighted the reference in the guidance which advised monitoring to include the following monitoring of temperature, blood pressure and heart rate which could not be done over the telephone and that GPs could be legally liable if these were not done. Ms Dakin highlighted the necessity of agreeing realistic monitoring in the community to address the shortfalls revealed in the RCAs and national guidance. In the event of a patient having a relapse then the advise of a Consultant Microbiologist should be sought.</p> <p>During discussion Dr Tooley referred to the need to make the monitoring realistic and that the key concern was to ensure that the correct information was conveyed to patients and that they knew how to make further contact. Dr Emslie highlighted that GPs should have access to the information which was sent to patients and that they should be seen again at least between days 4 and 6 and more frequently if indicated. Dr Tooley stated that there should be easy access to the guidance when GPs saw a patient and print off what they required.</p> <p>Dr Harris referred to an East Midlands Patient Information Leaflet which provided information to carers on how to manage patients at home.</p>	

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	<p>Agreed: JAPC agreed for the guidance to be brought back on the management of Clostridium Difficile after the inclusion of a GP checklist, availability of patient information, monitoring between days 4 and 6 based on GP discretion and that the advice of a consultant microbiologist should be obtained in cases of relapse within 28 days.</p> <p>Action: The wording of the document would be amended to indicate that relapses after 28 days would be classified as new infections.</p> <p>Action: The monitoring guidance would be amended in order to separate out the GP responsibilities.</p> <p>Action: The guidelines including the monitoring to be brought back to the April JAPC meeting.</p>	<p>DH</p> <p>DH S Dakin</p> <p>SD</p>
<p>d.</p>	<p><u>Hypomagnesaemia and Unlicensed/Off Label Use of Oral Treatments</u></p> <p>Mr Dhadli advised JAPC that NICE have started to produce evidence summaries on unlicensed and off label medicines and one of these was 'Preventing recurrent hypomagnesaemia: oral magnesium glycerophosphate'. Mr Dhadli queried whether JAPC would find these summaries to be useful and how guidelines, one of which was for oral treatment of hypomagnesaemia in adults, produced by the Southern Derbyshire Shared Care Pathology Group, should fit into the governance arrangements of the APC. The Evidence Review, which had looked at patients previously treated with IV infusion of magnesium, highlighted that all oral magnesium phosphate did not have a UK licence; there was no national guidance for the treatment and there were no published trials for placebo versus active treatment.</p> <p>Feedback had been received from Dr Stanworth, Consultant Endocrinologist, on the NICE evidence review and the condition being treated. Dr Stanworth had indicated that supplementation still had a role in the management of patients for example following cessation of PPI or to avoid recurrent admission in those patients with severe deficiency and previous IV treatment.</p> <p>During discussion Mrs Needham commented that all NICE Evidence summaries should initially go to the Guidelines Group which would then act as a filter to determine which of them should be considered by JAPC. Mr Anderton stated that the summaries offered an opportunity to make decisions about significant usage and review practice, but was unaware of these particular guidelines which were not in use at RDH. Dr Tooley added that the pathology guidelines were often used in primary care by GPs. Dr Bell commented that, as part of the review of JAPC, greater clarity would be required about the relationship with the Guidelines Group. Mr Shepherd commented that guidance which referred back to NICE guidance was acceptable but how this was conveyed to primary care was a locality issue. Dr Parkin suggested that the Shared Care Pathology Group be requested not to include any references to prescribing in any guidance issued.</p> <p>Mr Anderton highlighted that magnesium glycerophosphate did not feature in the guidelines whereas Maalox was widely available and provided enough magnesium in doses which were tolerated.</p>	

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	<p>Agreed: It was agreed that the awareness and governance of the Shared Care Pathology Guideline Group needed to be highlighted at RDH. Drug inclusions into these guidelines should be compliant with local JAPC formulary.</p>	<p>SD/ RDH</p>
<p>8.</p>	<p>SHARED CARE GUIDELINES</p>	
<p>a.</p>	<p><u>Melatonin</u> Mr Shepherd stated that the current shared care guideline for melatonin was due for review. A licensed form of melatonin (Circadin MR) was available and Mr Shepherd also referred to a lack of clarity about what should happen when patients reached age of 18 and transferred to adult services as the shared care guideline listed no explicit monitoring requirements and was limited to use in children. In addition melatonin only met one the agreed criteria for shared care status which was specialist initiation.</p> <p>Dr Parkin reported that the issue of the transfer over at age 18 had been discussed by the Learning Disabilities Clinical Reference Group and a draft transition document had been prepared which would be approved at the next meeting of this Group.</p> <p>Mr Anderton queried whether a traffic light classification of suggested green was appropriate for Circadin MR due to low level evidence and no published long term data. Circadin MR should be led by a specialist in secondary care and continued in primary care with clear communication about end points and monitoring. MTRAC had indicated that they did not consider a shared care to be necessary but could not recommend it in primary care as current evidence as to its efficacy was inadequate to support its use.</p> <p>Agreed: The shared care guideline would be extended to September 2013 to allow for the transition of patients to the licensed form of melatonin to be completed.</p> <p>Agreed: Circadin classified as a BROWN specialist initiation drug for off licence use in disabled children and CAMHs patients. It remains BROWN not recommended except in exceptional circumstances for its licensed indication in patients over 55.</p>	<p>SD</p> <p>SD</p>
<p>b.</p>	<p><u>Alcohol Abstinence</u> Mr Dhadli highlighted the following points in the shared care agreements: Disulfiram shared care – There was a need to clarify medical monitoring in the monitoring requirements and NICE guidance 115 referred to the need to monitor every two weeks for the first two months and then monthly for four months and this should be included. Acamprosate shared care – The monitoring required section currently referred to ‘none required’ and this should be removed.</p> <p>Dr Emslie queried the section in the disulfiram shared care which referred to liaison by GPs with the specialist alcohol services for any information or advice regarding disulfiram. Dr Taylor would amend the disulfiram shared care guideline and this would come back to the next meeting of JAPC.</p> <p>Agreed: The acamprosate shared guideline was ratified by JAPC with the minor</p>	<p>ST</p>

Item		Action
	agreed amendment included.	SD
9.	MONTHLY HORIZON SCAN	
a.	Mr Dhadli advised that JAPC had agreed to highlight all new drug launches and to agree the necessary action plan. The following action was agreed: Saxagliptin plus metformin 2.5/850mg and 2.5/1000mg - BROWN. Estradiol 1.5mg plus Nomegestrol 2.5mg – Not classified.	
10.	MISCELLANEOUS	
a.	<p><u>Guideline Group Terms of Reference</u> The Guideline Group terms of reference were noted for information.</p> <p><u>Use of Licensed Liquids</u> Mr Hulme informed JAPC that there were now an increasing number of licensed liquids available and previously options had been the crushing of tablets or using an unlicensed liquid special. It was highlighted that the licensed liquids were extremely expensive and MHRA guidance did not support the crushing of tablets or splitting of capsules except in exceptional circumstances. There was consequently a need for a position statement on this issue.</p> <p>Mr Dhadli referred to recent guidance from the General Medical Council which stated that a licensed product should be used wherever possible but, if an unlicensed product was chosen, the prescriber needed to be confident as to its safety and clinical efficacy. Mr Anderton stated that the Royal Pharmaceutical Society NEWT handbook contained a section on crushing tablets and also dispersal. Mr Hulme commented that some patients during consultation with their GP may prefer tablets to be crushed and this should be an option. Dr Tooley advised that a clinical statement was needed to allow for clinical judgement and, in the event that crushing tablets was more appropriate for a patient and this had been fully explained, then this would be acceptable. Mrs Needham advised that certain drugs for which crushing had been recommended may need to be reviewed.</p> <p>Agreed: JAPC noted the MHRA advice and accepted that the local guidelines will have to reflect this. JAPC also acknowledged the cost pressure of using some licensed specials and that, whilst MHRA guidance should be followed, clinicians will decide choice of formulations after an informed discussion with the patient.</p>	
11.	NICE TA GUIDANCE	
	<p>JAPC agreed the following statement for Derbyshire:</p> <p>'If a NICE technology appraisal recommends the use of a technology, it is as an option for the treatment of a disease or condition within Derbyshire and its Clinical Commissioning Groups (CCGs).The technology will be available for a patient who meets the clinical criteria set out in the guidance, subject to the judgement of the treating clinician. CCGs in Derbyshire will provide funding and resources when the treating clinician concludes and the patient agrees that the recommended technology is the most appropriate to use, based on a discussion of all available treatments.</p> <p>If a NICE technology appraisal states 'option for treatment', Derbyshire JAPC will</p>	

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	<p>adopt the medicine into the local formulary, and if necessary, identify its place in line with NICE recommendations. JAPC provides guidance on preferred drug options within its formulary and/or traffic light classification database list.'</p> <p>This statement would be placed on the website.</p>	SD
10.	NICE SUMMARY	
	<p>Mrs Qureshi informed JAPC of the comments for the CCGs which had been made for the following NICE guidance:</p> <p>TA 274 Ranibizumab for treating diabetic macular oedema – Estimated costs of the Derby City incident population for drug and monitoring: Year 1 - £46,000 Year 2 - £26,000 Year 3 - £19,000 For the Derby City prevalent population estimated costs of drug and monitoring: Year 1 - £461,000 Year 3 - £200,000</p> <p>For the County incident population the estimated costs of drug and monitoring: Year 1 - £128,000 Year 3 - £55,000 For the County prevalent population the estimated costs of drug and monitoring: Year 1 - £1.1 million Year 3 - £500,000</p> <p>Ranibizumab classified as a RED drug (NICE TA 274).</p> <p>NICE TA 275 – Apixaban for preventing stroke and systemic embolism in people with nonvalvular atrial fibrillation. This was previously discussed as agenda item E.</p> <p>Apixaban classified as RED (NICE TA 275 for AF).</p> <p>CG 156 Fertility – Noted by JAPC.</p>	
11.	JAPC BULLETIN	
	<p>The following amendments were agreed:</p> <p>Cerelle classified as a GREEN first line drug desogestrel preparation.</p> <p>Opportunistically detecting atrial fibrillation during diagnosis and monitoring of hypertension – Change wording to 'The decision to adopt this guidance should be made at CCG, locality or practice level.'</p> <p>The amended JAPC bulletin was ratified by JAPC.</p>	SD
12.	GUIDELINE GROUP	
	<p>The Guideline Group action tracker was ratified by the JAPC.</p>	

Item		Action
13.	TRAFFIC LIGHTS – ANY CHANGES?	
	<p><u>Classifications</u></p> <p>Co-enzyme Q10 – Sheffield Area Prescribing Committee had classified Co-enzyme Q10 as red for use in the treatment of Friedrich’s ataxia and black for any other indication. JAPC endorsed this decision.</p> <p>Bromfenac – RED</p> <p>Loteprednol – RED</p> <p>Apixaban – RED</p> <p>Circadin – BROWN specialist initiation</p> <p>Rivaroxaban – GREEN specialist initiation for DVT/PE</p> <p>Ranibizumab - RED</p>	
14.	ACTION SUMMARY	
	<p>The action summary was noted by JAPC and amendments made:</p> <p>Disulfiram shared care – To be re-considered by JAPC.</p> <p>Vitamin D – Take off.</p> <p>Co-enzyme Q10 – Take off.</p> <p>Lipid and FH Policies – Working Group to produce recommendations for update of lipid/FH policies.</p> <p>JAPC Review – Whole day to be used on the day scheduled for May JAPC meeting (14th May).</p>	<p>SD</p> <p>SD</p> <p>SD</p> <p>SD</p> <p>SD</p>
15.	MHRA DRUGS SAFETY UPDATE	
	<p>The MHRA Drug Safety Alert for February 2013 was noted.</p> <p>Mr Dhadli highlighted that cases of atypical femoral fracture had been reported rarely in patients with postmenopausal osteoporosis receiving treatment with denosumab 60mg after long-term treatment. Mr Dhadli had updated the shared care accordingly and one of the shared care authors would provide guidance for health care professionals and patients for the reporting of certain signs and symptoms.</p>	
16.	MINUTES OF OTHER PRESCRIBING GROUPS FOR INFORMATION	
	<ul style="list-style-type: none"> • Sheffield Area Prescribing Committee 20/11/12 • Derbyshire Healthcare Foundation Trust Drugs and Therapeutic Committee 24/1/13 	
17.	ANY OTHER BUSINESS	
	<p>Mr Dhadli highlighted the lack of both GP input and involvement of Chesterfield Royal Hospital in the development of the diabetes guidance. It was agreed that Mr Shepherd would nominate a representative from CRH and the CCGs would nominate a GP representative and inform Mr Dhadli accordingly.</p>	<p>MS/ CCGs</p>

For agenda items contact Slakahani Dhadli
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Item		Action
18.	DATE OF NEXT MEETING	
	Tuesday, 9 April 2013 at 1.30 pm in the Birchwood Room, Post Mill Centre, South Normanton.	