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DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Minutes of the meeting held on 14th June 2016

CONFIRMED MINUTES

Summary Points

Traffic lights

Drug	Decision
Tiotropium + olodaterol inhaler (Spiolto Respimat) for COPD	BLACK
Guanfacine	RED
Cabazitaxel	RED as per NICE TA 391

Clinical Guidelines

Buccal Midazolam Information Sheet
Oral Nutrition Support (ONS) Guidelines for Adults
Actinic Keratosis

Patient Group Directions

Haemophilus influenzae type B and meningococcal C conjugate vaccine (Hib/MenC)

Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) (PCV)

Zostavax® reconstituted lyophilised suspension. Shingles (herpes zoster) vaccine, live

Low dose diphtheria, tetanus, acellular pertussis and inactivated poliomyelitis vaccine (dTaP/IPV) - Women from 20 weeks of pregnancy in accordance with the pertussis vaccination for pregnant women national immunisation programme

Human papillomavirus vaccine [Types 6, 11, 16, 18] (Recombinant, .adsorbed) (HPV) - Females from 12 years of age or from school year 8 in accordance with the national immunisation programme

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Present:	
Southern Derbyshire CCG	
Dr A Mott	GP (Chair)
Mr S Dhadli	Specialist Commissioning Pharmacist (Secretary)
Mrs L Hunter	Assistant Chief Finance Officer
Mr S Hulme	Director of Medicines Management (also representing Erewash CCG)
Mrs S Qureshi	NICE Audit Pharmacist
Dr M Watkins	GP
North Derbyshire CCG	
Dr T Narula	GP
Mrs K Needham	Head of Medicines Management North (also representing Hardwick CCG)
Ms J Town	Head of Finance
Hardwick CCG	
Dr T Parkin	GP
Erewash CCG	
Dr M Henn	GP
Derby City Council	
Derbyshire County Council	
Derby Teaching 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 Foundation Trust	
Mr M Steward	Head of Medicines Management
In Attendance:	
Mr A Thorpe	Derby City Council (minutes)

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Item		Action
1.	**APOLOGIES**	
	Dr R Dewis and Dr C Emslie.	
2.	**DECLARATIONS OF CONFLICT OF INTEREST**	
	No declarations of interest were made.	
3.	**DECLARATIONS OF ANY OTHER BUSINESS**	
	No declarations of any other business were made.	
4.	**MINUTES OF JAPC MEETING HELD ON 10 MAY 2016**	
	The minutes of the meeting held on 10th May were agreed as a correct record after the following amendments: Benzbromarone – Amend to: 'It was noted that benzbromarone was unlicensed in the UK and required some degree of monitoring. Agreed: Benzbromarone classified as a RED drug. Management of Heart Failure Mr Dhadli advised that two versions of the guidance had been produced: Management of Heart Failure with Reduced Ejection Fraction (HFREF) and Management of Heart Failure with HFREF that included sacubitril valsartan. Fosfomycin – Amend to: Mr Newman advised that supplies of fosfomycin could be obtained by community pharmacists from the DTHFT pharmacy.	
5.	**MATTERS ARISING**	
a.	**<u>Ulipristal</u>** Mr Dhadli reported that Dr Parratt had now replied to the queries from the Guideline Group which had been referred to at the last meeting as follows: • What treatment should have been tried before a patient was referred into the pathway suggested? *A range of treatments would have been tried in primary care dependent on the symptoms - usually menorrhagia or abdominal discomfort. A reference to the heavy menstrual bleeding pathway could be included in the guidance.* • Which sections in the flowchart should be for acute use? *Pre-operative and infertility pathway.* • How many cycles should be given to a patient? *The clinical trials go up to eight cycles but two to three courses would normally be considered sufficient.* • What advice should be given to GPs about clinical criteria when referring back to secondary care while a patient was on treatment? *This was included in the guidance and there was some reference on the first sheet.* • Clarification of responsibility for undertaking ultrasound scans. *Once the care had been handed over these would be carried out by primary care.* • An idea of patient numbers for North and South Derbyshire in order to determine budget impact. *There were no patient numbers.* These comments would be incorporated into the guidance and reviewed again by the Guideline Group in the light of the forthcoming NICE CG.	**SD**

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b.	**Management of Heart Failure** Mr Shepherd stated that a reply was still awaited from Dr P Masters concerning the serum peptide level recording at CRHFT - this would be picked up by the CRHFT Drugs and Therapeutic Committee. There had been some further email correspondence about the guidelines from the DCHSFT heart failure nurses, but no further requests had been received so the guideline stood as previously agreed.	
c.	**Fosfomycin** Mr Hulme advised that Derbyshire Health United (DHU) had been asked whether they could stock a supply of fosfomycin but they had declined to do this. It was noted that supplies of fosfomycin could be obtained by community pharmacists from the DTHFT pharmacy. In the meantime the South Derbyshire Prescribing Group would discuss the supply issues further and there would also be further discussion with DHU. It was noted that the fosfomycin guidance had now been placed on the website.	**SH**
d.	**Osteoporosis Guideline** Mr Dhadli reported the local osteoporosis guidance expired in 2014 and were last looked at in 2012. It appears that there are delays to NICE with no definite date for their guideline review. In light of this Mr Dhadli has looked to re-write our local guidance and sought feedback from CRHFT and DTHFT on whether the FRAX screening tool should be used for primary prevention (10% risk over 10 years), risk factors for treatment and referrals for DEXA scanning should be included in the updated osteoporosis guideline. Mr Dhadli would forward the email sent to Dr Stanworth to Dr Goddard on key proposed changes before embarking on the production of a new guideline. CRHFT had already responded accepting the proposal.	**SD**
6.	**NEW DRUG ASSESSMENTS**	
a.	**Olodaterol and Tiotropium and Olodaterol** Olodaterol (monotherapy) drug review. This covered a previous decision and would inform JAPC before consideration of the combination inhaler. Mr Dhadli stated that olodaterol (Striverdi Respimat) was a once-daily long-acting beta-2 agonist (LABA) for chronic obstructive pulmonary disease (COPD) and had been assigned a traffic light classification by JAPC of BLACK in March 2015. Olodaterol had been the subject of two reviews from the Scottish Medicines Consortium (SMC) published in August 2014 and the NICE New Medicine Review in February 2015. Both reviews had looked at two 48 week studies and the reviews had excluded the non-licensed dose. The SMC had originally rejected olodaterol on clinical and economic grounds and had concluded that there was no significant difference between olodaterol 5mcg and another LABA for the primary endpoints of trough FEV1 and FEV1 AUC (0-3 hours) at week 24. Subsequently the company had re-submitted a cost-minimisation analysis to SMC in September 2014 and it had then been accepted. There had been a subsequent DTB review which had used the same evidence from the same studies. Mr Dhadli referred to the efficacy results in the DTB review which summarised the main studies against placebo, and also versus formoterol, and that JAPC had made its traffic light decision due to lack of data on effectiveness compared with standard therapy and cost-effectiveness compared with standard therapy.	

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	In terms of patient factors it was highlighted that olodaterol was administered once-daily using the Respimat Soft Mist Inhaler device rather than the dry powders used in the other drugs. It was also noted that formulary formoterol was significantly cheaper than olodaterol, indacaterol and salmeterol. Mr Dhadli advised that tiotropium and olodaterol (Spiolto Respimat) was a combination LABA+LAMA product. It was noted that JAPC had both tiotropium products (Spiriva Handihaler and Spiriva Respimat) as the preferred formulary LAMA and that olodaterol + tiotropium is the first LABA/LAMA combination to include tiotropium. The main evidence used by NICE ESNM (Evidence Summary of New Medicine) came from two 52‑week double-blind, randomised controlled trials (RCTs) comparing tiotropium/olodaterol with the individual mono-components tiotropium and olodaterol in people with COPD across 25 countries. The primary outcomes (FeV1, SGRQ) in these trials were assessed after 24 weeks' treatment and for secondary outcomes of transition dyspnoea index (TDI) had been used. Mr Dhadli referred JAPC to the NICE Evidence Summary of New Medicine Review on tiotropium/olodaterol and the regulatory authority COPD guidelines which stated that each drug in a fixed-dose combination must make a documented contribution within the combination to the claimed effects. The fixed-dose combination must therefore demonstrate a clinically relevant improvement in lung function and symptomatic improvement over the mono-components. Results from the studies for lung function improvement were in the main non-clinically significant (<100mls). However, NICE review did state that improvements seen with tiotropium/olodaterol were in-line with other currently available LAMA/LABA combination inhalers. During discussion Dr Henn commented that the combination product did not offer any significant improvements over the existing products and was not particularly user friendly. Dr Narula queried how often a LAMA/LABA combination would be used and was informed that its place in therapy was limited. Dr Henn added that there was over-prescribing of inhaled steroids for COPD and therefore a number of patients who did not benefit from these may find LAMA/LABA products more beneficial. However there could be a risk of over prescribing of LAMA/LABA but this may offer an option for use in those patients who cannot use a dry powder device. Dr Mott summarised by referring to the current traffic light classifications of olodaterol as BLACK and its direct once daily LABA comparator indacaterol as BROWN, although the latter was a more expensive LABA compared to formoterol. It was queried whether indacaterol was more effective than olodaterol and whether the combination product of tiotropium and olodaterol offered any significant benefits over formoterol/aclidinium and indacaterol/glycopyrronium both of which had been assigned a traffic light classification of BROWN. **Action:** A review to be undertaken of all the LAMA/LABA products and the views of the DTHFT and CRHFT respiratory consultants would be obtained.	**SD**

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	Agreed: Olodaterol to remain classified as a **BLACK** drug pending a review of all the LAMA/LABA products and the outcome of discussions with the respiratory consultants. JAPC classified the combination tiotropium/olodaterol inhaler (Spiolto Respimat) as **BLACK** pending this review.	**SD**
b.	**Guanfacine** Dr Taylor advised that the DHcFT community paediatricians favoured its use as an option when a non-stimulatory drug was indicated. Work was proceeding on a shared care request. Dr Mott commented that the place of guanfacine in the ADHD treatment pathway, together with the cohort of patients to be treated with this drug instead of atomoxetine, would need to be determined. Mr Dhadli reported that guanfacine (Intuniv®) was a selective alpha2–adrenergic receptor agonist and non-stimulant for the treatment for children and young people with attention deficit hyperactivity disorder (ADHD). It was in the same drug class as clonidine which was used off-licence by tertiary centres and was an option to existing treatments if these were found to not be suitable, not tolerated or shown to be ineffective. The NICE guideline on ADHD indicated that drug treatment for children and young people with ADHD should always form part of a comprehensive treatment plan that included psychological, behavioural and educational advice and interventions. Where drug treatment was considered appropriate the guideline had recommended methylphenidate, atomoxetine and dexamfetamine, within their licensed indications, as options for the management of ADHD in children and young people. The evidence for guanfacine came from short term studies no longer than 13 weeks. The NICE review covered primarily three short-term, randomised controlled trials which had demonstrated that guanfacine was more effective than placebo at improving ADHD-RS-IV symptoms, although a beneficial effect on impairment and social functioning had not been consistently shown. It had not been directly compared to other active treatments and there were two open-label long-term studies which showed effectiveness for up to two years but without a placebo arm. However there had been a very significant number of withdrawals (80%). Dr Mott commented that an option would be to classify guanfacine as RED and request a treatment algorithm to define its place in therapy. In addition the shared care would need further discussion. Mr Dhadli expressed some concern about the potential long term safety of this drug and Mr Shepherd advised that guanfacine had been discussed by CRHFT Drugs and Therapeutic Committee and a decision made that it could be used second or third line in cases of unsuitability or intolerance after a stimulant treatment had been tried. Mr Steward suggested that guanfacine could be classified as a RED drug with the stipulation that a report was produced after six months use about the type of patients it had been used for before a shared care could be considered. Mr Hulme queried the cost effectiveness of the drug and highlighted that shared care could increase the numbers. Mrs Needham added that the requirement to monitor patients every three months would have an additional effect on activity in the event that they did not attend for this time period.	

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	Agreed: Guanfacine classified as a **RED** drug as it was new to clinical practice and required a period of accumulation of experience by consultants/specialists.	**SD**
7.	**CLINICAL GUIDELINES**	
a.	**Buccal Midazolam Information Sheet** Mr Dhadli reported that Ms Gaynor Ward, DHcFT Nurse Consultant for Learning Disabilities, had produced an information sheet on the management of emergency rescue medication (buccal/oromucosal midazolam) for children, young people and adults with prolonged or repeated generalised, convulsive (tonic–clonic, tonic or clonic) seizures in the community. Dr Taylor highlighted that there was a lack of knowledge by non-medically trained carers of learning disability users about the administration of buccal midazolam for the control of prolonged or continuous seizures. A care plan had been attached to the information sheet for completion by the prescriber following administration of buccal midazolam to indicate the epilepsy management plan/emergency epilepsy plan. Dr Mott queried whether GPs would complete this form and Dr Parkin suggested that a tick box be included in the annual health check template to indicate whether a management plan was in place if a patient was on buccal midazolam – this was agreed. There were two buccal midazolam products available: Buccolam® was the licensed drug for use in children (3 months – 18 years) and Epistatus which was unlicensed in both children and adults. Derbyshire was moving to one preferred buccal midazolam product (the licensed version, Buccolam) for use in both adults (off-licence use) and children (licensed use). However it was noted by Mrs Needham that current levels of prescribing of the unlicensed Epistatus still remained consistently high. It was therefore agreed Mrs Needham would draft a letter to be sent to Ms Ward about this issue to be signed by Dr Mott. **Agreed:** JAPC ratified the Buccal Midazolam Information Sheet.	**KN/AM** **SD**
b.	**Oral Nutrition Support (ONS) Guidelines for Adults** Mr Dhadli advised that Ms Janice Barratt, Southern Derbyshire CCG Medicines Management Dietitian, had produced a revised version of the Oral Nutrition Support (ONS) Guidelines for Adults. Mr Dhadli added that the main changes concerned appendix 3, which listed the standard ONS products for adults by category and cost/100kcal, and appendix 1 which referred to revised clearer MUST score. In connection with appendix 3, Mrs Needham referred to discussion at the Guideline Group about Foodlink Complete and whether this was available and could be prescribed. In addition, the list should indicate which are the preferred products and cheapest in each category. It was suggested that a statement should be added at the top of each section to indicate that the most cost effective suitable product should be used. **Agreed:** JAPC ratified the Oral Nutrition Support (ONS) Guidelines for Adults with the agreed amendment to appendix 3.	**SD** **SD**

Item		Action
8.	**PATIENT GROUP DIRECTIONS**	
	The revised Public Health England/NHS England Patient Group Directions for the following PGDs were noted and agreed by JAPC: • Haemophilus influenzae type B and meningococcal C conjugate vaccine (Hib/MenC) – to replace the previous PGD which was due to expire in June 2016. • Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) (PCV) – to replace the previous PGD which was due to expire in September 2016. • Zostavax® reconstituted lyophilised suspension. Shingles (herpes zoster) vaccine, live – version 4, update to the previous version 3. • Low dose diphtheria, tetanus, acellular pertussis and inactivated poliomyelitis vaccine (dTaP/IPV) - Women from 20 weeks of pregnancy in accordance with the pertussis vaccination for pregnant women national immunisation programme – version 2, update to version 1. • Human papillomavirus vaccine [Types 6, 11, 16, 18] (Recombinant, adsorbed) (HPV) - Females from 12 years of age or from school year 8 in accordance with the national immunisation programme – to replace the previous PGD which was due to expire in July 2016. Mr Steward queried the very short expiry date for the shingles PGD – this would be checked by Mr Dhadli.	**SD**
9.	**MONTHLY HORIZON SCAN**	
	Mr Dhadli advised JAPC that drug discontinuations were a standing item in the horizon scan document and queries concerning the prescribing of these were monitored by the medicines management team: For example - ePACT data suggested low level prescribing of Beta-Adalat (atenolol/nifedipine).	
10.	**MISCELLANEOUS**	
a.	**<u>Prescribing in Primary Care</u>** Mr Dhadli reported that this resource document was for use by practice pharmacists and GPs based on queries received about prescribing related issues and had been updated. The main changes were: • Page 5 - NHS England has provided specific information to general practitioners on their responsibilities in prescribing and monitoring hormone therapy for transgender and non-binary adults. • Page 6 – Addition of the JAPC definition for BLACK drugs. • Page 9 - Management of repeat prescriptions – Addition of advice from the Royal Pharmaceutical Society that requests for repeats must be triggered by the patient and decisions to reorder are not taken by pharmacy or other staff without input from the patient. • Page 14 – New section added concerning NHS patients being seen by private providers. • Appendix 2 – Items that should be prescribed by brand name for safety reasons. • Appendix 6 – PrescQIPP Travel Vaccine Bulletin and the view of the Derbyshire Local Medical Committee.	

Item		Action
	Dr Parkin and Dr Watkins expressed strong concern that the recommendation in section 10.1 on page 9 that community pharmacies and other companies requesting prescriptions on behalf of patients should have discussed the need for further repeat items with the patient or carer not earlier than five working days prior to submitting the repeat request was not being adhered to. It was highlighted that this was a national issue and required further discussion in order to achieve a resolution. In the meantime the need to include this requirement in communications to pharmacists was highlighted. **Action:** To be taken via the Prescribing Groups for dissemination.	**KN/SH**
b.	**Regional Medicines Optimisation Workshop** Mr Dhadli reported that a Regional Medicines Optimisation Workshop had been held in April following the publication of the letter from Dr Keith Ridge, Chief Pharmaceutical Officer, in February 2016 to the four Regional Medical Directors of England about the establishment of Regional Medicines Optimisation Committees. The outputs from the workshop were noted by JAPC.	
11.	**JAPC BULLETIN**	
	The bulletin was ratified by JAPC.	
12.	**MHRA DRUG SAFETY UPDATE**	
	The MHRA Drug Safety Alert for May 2016 was noted and items relating to primary care were discussed. Mr Dhadli highlighted the following Direct Healthcare Professional Communication: • Letters had been sent to healthcare professionals in April 2016 regarding canagliflozin containing medicines (Invokana▼, Vokanamet▼) to highlight the risk of lower limb amputation (primarily of the toe). Mr Dhadli highlighted the following MHRA advice: • BCR-ABL tyrosine kinase inhibitors: risk of hepatitis B reactivation. • Pomalidomide (Imnovid▼): risk of hepatitis B reactivation. • Retigabine (Trobalt): risk acquired vitelliform maculopathy. It was noted that this had a JAPC traffic light classification of RED. • Issue involving the QRISK®2 calculator run by TPP which was used by some GPs to assess the potential risk of cardiovascular disease in patients as part of their overall evaluation. The issue has resulted in incorrect results being produced for a limited number of patients but had now been fixed by TPP. GPs would contact those patients who had incorrect scores, identify those who may benefit from being reassessed and, if required, discuss the different approaches they could take to reduce their risk of cardiovascular disease.	
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 2016.	

Item		Action
	TA217 updated Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease – All of these drugs had been assigned a traffic light classification of AMBER apart from rivastigmine which was also GREEN after consultant/specialist initiation for PDDC. TA390 Canagliflozin, dapagliflozin and empagliflozin as monotherapies for treating type 2 diabetes – These were now recommended as monotherapy options for treating type 2 diabetes in adults for whom metformin was contraindicated or not tolerated and when diet and exercise alone did not provide adequate glycaemic control only if dipeptidyl peptidase-4 (DPP-4) inhibitor would otherwise be prescribed and a sulfonylurea or pioglitazone was not appropriate. Canagliflozin, dapagliflozin and empagliflozin would be included in the diabetes guidance and were currently classified as BROWN on specialist initiation. Mr Dhadli advised that a query had been raised with NICE about the positioning of this monotherapy treatment and that one of the diabetes consultants had proposed that empagliflozin should be the preferred drug ahead of the other two. This was due to the cardiovascular evidence base emerging with empagliflozin and the MHRA alert concerning the risk of lower limb amputation with canagliflozin. TA391 Cabazitaxel for hormone-relapsed metastatic prostate cancer treated with docetaxel – This had previously been classified as BLACK as NICE had not recommended it. However it was now recommended by NICE – classified as a **RED** drug.	**SD**
14.	**TRAFFIC LIGHTS – ANY CHANGES?**	
	Classifications Tiotropium + olodaterol inhaler – **BLACK** Guanfacine – **RED** Cabazitaxel – **RED** as per NICE TA 391	
15.	**JAPC ACTION SUMMARY**	
	The action summary was noted by JAPC and amendments made: Ulipristal for uterine fibroids – To be taken off the list and reviewed in the light of the NICE guidance expected in August 2016. Diabetes Type 2 Guidance – Mrs Qureshi advised that the guidance was ready to be discussed by the Guideline Group although a reply was still awaited from Dr F Game. Dr Goddard would contact Dr Game about this. PCSK9 inhibitors – To be brought to the July 2016 JAPC meeting. Combination Inhalers for COPD (LAMA + LABA) – To be brought to a future JAPC meeting. Buccal Midazolam – Dr Mott and Mrs Needham to contact Ms Gaynor Ward about the licensed/unlicensed product issue.	**SD** **WG** **SD** **SD** **AM/KN**

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16.	**GUIDELINE GROUP ACTION TRACKER**	
	The summary of key messages from the Derbyshire Medicines Management Guideline Group meetings held in May and June 2016 to be discussed at the July JAPC meeting.	**SD**
17.	**MINUTES OF OTHER PRESCRIBING GROUPS**	
	• Nottinghamshire Area Prescribing Committee 21/01/16 • Nottinghamshire Area Prescribing Committee 17/03/16 • DHcFT Drugs and Therapeutic Committee 24/03/16 • DTHFT Drugs and Therapeutic Committee 19/04/16 • Clinical Commissioning Policy Advisory Group 17/04/16 • Burton Drugs and Therapeutic Committee 09/05/16 • Chesterfield Drugs and Therapeutic Committee 17/05/16 It was noted that the Clinical Commissioning Policy Advisory Group minutes would now be included when available.	
18.	**ANY OTHER BUSINESS**	
a.	Dr Goddard advised that an increase in the number of referrals for endoscopy for dyspepsia had been highlighted at a recent gastroenterology meeting and it had been suggested that this could be linked to an unintended consequence of the new dyspepsia guidance or the reduction in the prescribing of proton pump inhibitors (PPIs). Mr Hulme referred to the PINCER trial and the recommendation to use the PPIs as gastoprotection when NSAIDs are required and therefore it is likely that there will be increased prescribing of PPIs. It was agreed that the increase was more likely to be linked to the new NICE Cancer referral guidance (lowering the threshold) and referrals made by staff such as junior staff and locums. Dr Goddard commented that this issue would be further explored. Mrs Hunter queried whether the provision of endoscopies at Ilkeston Community Hospital had been withdrawn. Ms Town highlighted that this was a temporary measure only due to staffing issues.	
b.	JAPC noted that this would be the last meeting to be attended by Mr Steward and thanks were expressed for his work on the committee and its predecessors. Best wishes were expressed to Mr Steward for a long and happy retirement. Mr Steward advised that the Deputy Head of Medicines Management would represent DCHSFT at JAPC meetings until September 2016 when Anna Braithwaite would take over.	
19.	**DATE OF NEXT MEETING**	
	Tuesday, 12th July 2016 at 1.30pm in the Post Mill Centre, South Normanton.	