Northern, Eastern and Western Devon Clinical Commissioning Group South Devon and Torbay Clinical Commissioning Group

University Hospitals Plymouth

NHS Trust

Meeting of the South and West Devon Formulary Interface Group Minutes

Wednesday 16th January 2019: 2:00 pm – 4.30 pm The Watermark, Erme Court, Leonards Road, Ivybridge PL21 0SZ

Present: Peter Rowe (Chair)

Consultant

Andy Craig	GP	NEW Devon CCG
Emma Gitsham	Joint Formularies Pharmacist	NEW Devon CCG
Lily Hammarlund-Sim	Pharmaceutical Advisor	NEW Devon CCG
Matt Howard	Clinical Evidence Manager	NEW Devon CCG
Paul Humphriss	Advanced Clinical Pharmacist	Livewell Southwest
Tom Kallis	Community Pharmacist	
Sarah Marner	Senior Medicines	NEW Devon CCG
	Optimisation Pharmacist	
Hilary Pearce	Clinical Effectiveness Pharmacist	NEW Devon CCG
lain Roberts	Lead MO Pharmacist	South Devon & Torbay CCG
Graham Simpole	Joint Formularies Support Pharmacist	NEW Devon CCG
Darren Wright	Joint Formularies Technician	NEW Devon CCG
Observers:		
Yin Ki Ng	Senior Medicines Optimisation	South Devon & Torbay CCG
	Pharmacist	
Dany Ros	Practice Based Pharmacist	South Devon & Torbay CCG

In attendance:

Fiona Dyroff	Clinical Effectiveness	NEW Devon CCG
	Governance Support Officer	

1. Welcome and announcements

Dr Peter Rowe had taken over as Chair of the meeting following Dr Andrew Gunatilleke's decision to step down.

Those present introduced themselves.

Apologies

Trudy Bown	Chief Pharmacy Procurement & IT Manager	University Hospitals
		Plymouth NHS Trust
Bill Nolan	GP	SD&T CCG
Nicola Joyce	Pharmacist	Livewell Southwest
Tony Perkins	Senior Medicines Optimisation Pharmacist	NEW Devon CCG

Declaration of Interests

Declarations of Interest were collected and reported. The Declarations made did not result in anyone being excluded from the meeting or from the discussion of any item. All Declarations of Interest are reported in the minutes.

DRUG INCLUDED ON AGENDA	COMPANY / MANUFACTURER
Shared care Guidelines:	
Hydroxychloroquine	Various manufacturers
Cilodex® ear drops	Novartis Pharmaceuticals UK Ltd
Alternative treatments	Various manufacturers
Cholurso [®] (ursodeoxycholic acid) 250mg	HFA Healthcare Products Ltd
tablets	
Emollient review	
Various products	Various manufacturers
NHS England OTC guidance	
Various medications	Various manufacturers
Gout	
Various medications	Various manufacturers
Depression guidance update	
Various medications	Various manufacturers
Palliative care tables update	
Various medications	Various manufacturers
Lyme Disease	
Various medications	Various manufacturers
Various medications	Various manufacturers

Name	Declaration
Tom Kallis	Any other interests (including personal or family medical conditions) which could be seen as influencing view of the drug(s) under consideration.
	 Use of emollients for Eczema Family member has had Lyme disease in the last year Family member has gout
Darren Wright	Received samples of emollients that could have an overall cost in excess of £50 from Fontus Health and Zeroderma.

2. Minutes of the meeting held on Wednesday 14th November 2018 and matters arising

The minutes of the meeting held on Wednesday 14th November 2018 were approved.

Summary of actions			
	Action	Lead	Status
18/56	Timings of doses of antimicrobials to be standardised to the number of times per day throughout the antimicrobial guidance except for if there are clinical reasons not to.		Complete
	This is updated as NICE produce new guidance. The Formulary team have added this to the work plan and will ensure that it is completed in a timely manner.		
18/97	Finalised West Devon SMS guideline for DMARDs in rheumatology to be circulated.		Complete
18/98	Acute otitis media in children and young people – update to be published.		Complete
18/99	Lyme disease – consider the output of the Antimicrobial Stewardship Group and discuss with Phil Melluish and Paul Humphriss.		Complete
18/100	Add proposed entry for Trelegy Ellipta to the formulary in line with the discussion.		Complete
18/101	Add proposed entry for Insulin Degludec (Tresiba) to the formulary in line with the discussion.		Complete
18/102	Add agreed updated formulary entry for Kyleena (levonorgestrel) 19.5mg IUS to the formulary.		Complete
18/103	Cetraxal [®] (ciprofloxacin) 2mg/ml ear drops: Contact microbiologists to seek advice on whether a steroid is needed and progress item via e-FIG.		Complete
	This item was included on the agenda.		

18/104	Formulary entry for ulipristal acetate 5mg (Esmya) to be reclassified from 'Amber' to 'Red' in line with the discussion.	Complete
18/105	Ciclosporin drug entry 8.2.2 to be split into two separate entries. Oral and I/V ciclosporin preparations will remain in Chapter 8, Malignant disease. Ciclosporin eye preparations to move to Chapter 11.	Complete
18/106	Accepted formulary guidance for Infantile Colic to be added to the formulary.	Complete
18/107	Trudy Bown to be contacted to ascertain if Infacol can be removed from the formulary.	Complete
18/108	Unipolar depression – formulary team to redraft guidelines in line with discussion, liaise with specialists and bring back to future FIG meeting.	Complete
18/109	Formulary entry for anal irrigations systems to be added in line with the discussion.	Complete
18/110	Accepted formulary entry for anal inserts to be added to the formulary.	Complete
18/111	MHRA Drug Safety Update: October 2018 – Rivaroxaban (Xarelto $\mathbf{\nabla}$) – add agreed information to the formulary.	Complete
18/112	MHRA Drug Safety Update: October 2018 – Ritonavir containing products – add agreed information to the formulary.	Complete
18/113	MHRA Drug Safety Update: October 2018 – Link to the update to be added to the transdermal fentanyl entry for reference.	Complete
18/114	Venue for FIG meetings scheduled for 13 March 2019 and 10 July 2019 to be confirmed.	Complete
18/115	Add Medical Cannabis information to the work plan.	Complete
	This has been passed to the Medicines Optimisation Team who are considering whether any further work is needed.	
18/116	Medical cannabis: Comments on the letters (including Sativex to be fed back to local specialists and re-drafted letters forwarded to the formulary team.	Complete
	This has been forwarded to the Medicines Optimisation for consideration and to disseminate as appropriate.	

Matters arising

The title of Chapter 8 of the formulary, Malignant Disease, was discussed. It was agreed that this may be misleading as the Chapter is not limited to this. It was agreed that the Chapter be re-named: Malignant Disease and Immunomodulatory Drugs.

ACTION: Formulary Team to rename Chapter 8 of the Formulary in line with the discussion.

3. Hydroxychloroquine for rheumatological and dermatological conditions

The Royal College of Ophthalmologists (RCO) has issued new guidance for hydroxychloroquine retinopathy. This is because previously, evidence suggested that hydroxychloroquine retinopathy was

very rare and it was considered that insufficient evidence existed for the benefits of detecting hydroxychloroquine retinopathy at an early stage. However, recent epidemiological data indicate that the prevalence of toxicity amongst long-term hydroxychloroquine users may be around 7.5%. This risk may be as high as 20% to 50% in those taking the drug for more than 20 years, depending on the summation of risk factors in particular individuals. Additionally, the tests used to diagnose hydroxychloroquine retinopathy can detect pre-symptomatic disease, and reduce the risk of progression of visual loss by detecting disease at an early stage.

Currently patients receiving hydroxychloroquine are required to undergo an annual visual acuity test with a high street optometrist. The new recommendations require baseline and annual review of patients at high risk of hydroxychloroquine retinopathy using tests which are not available to high street optometrists, who are no longer accepting these patients for annual review, and require interpretation by an ophthalmologist. All patients require annual ophthalmological review after five cumulative years of treatment. In addition, selected patient groups require annual monitoring from an earlier stage in treatment.

The Clinical Commissioning Groups (CCGs) are undertaking the work required to commission a service to monitor for hydroxychloroquine retinopathy. The commissioning position in response to this guidance will be discussed at the January 2019 meeting of the Devon Clinical Policy Committee (CPC).

The Specialist Medicines Service (SMS) guideline for hydroxychloroquine is based on the new guidance from RCO. The latest British Society for Rheumatology (BSR) guidance for the monitoring of diseasemodifying anti-rheumatic drugs (DMARDS) published in 2017 were written in collaboration with the RCO with the intention of updating the recommendations to reflect any changes that may arise from work conducted by RCO. The BSR Guideline Development Group recommended formal retinal assessment, ideally, ideally using optical coherence tomography (OCT), as baseline and annually commencing after five years of treatment. NICE Clinical Knowledge Summaries (CKS) has the same recommendations for monitoring patients receiving hydroxychloroquine.

It was noted that this item had been brought to the FIG for early review and to seek GP advice, it will return to FIG at a later date. The FIG were asked to consider the content of the proposed SMS guideline for hydroxychloroquine together with the most pragmatic method for primary care to ensure that a patient referred for an annual ophthalmological review has been reviewed and that it is appropriate to continue prescribing hydroxychloroquine.

The FIG considered these questions, there was discussion about:

- Where responsibility sits in relation to the proposed SMS guideline. These fall into three areas; specialists (rheumatologists and dermatologists), ophthalmologists and GPs.
- It was noted that baseline tests can take time to complete and this guideline may increase demand for ophthalmological services which are already stretched. Concern was also expressed about delaying commencement of treatment. The chair reported that the Ophthalmology Lead at University Hospital Plymouth NHS Trust felt it was unnecessary to wait until baseline test results are received before starting the drug. The FIG agreed that the specialist should start and continue to prescribe until the baseline test results have been received. It was noted that the national guidance states that baseline screening should take place within 6-12 months of commencing treatment.
- There are alternatives to hydroxychloroquine. Hydroxychloroquine should only be given to patients for whom there is no alternative.
- There was discussion about annual follow-up screening and the need to for clarity about who is responsible for ensuring that this takes place.

• The Local Medical Committee (LMC) and specialists (rheumatologists and dermatologists) will be asked for their views before the next draft guidance is produced.

ACTION: Formulary team to take draft guidance to the LMC and also to specialists for their views. The guidance will then be brought back to the FIG together with the outcome from the forthcoming Clinical Policy Committee (CPC) meeting.

4. Consideration of Cilodex® (ciprofloxacin 3mg/ml & dexamethasone 1mg/ml) ear drops, suspension

At the last meeting the FIG was asked to consider ciprofloxacin 0.2% ear drops (Cetraxal) for inclusion into the formulary. It was agreed that further work be undertaken. Specialist opinion has suggested that Cilodex ear drops are the preferred option for acute otitis externa (AOE) and acute otitis media in patients with tympanostomy tubes (AOMT) and it has therefore been decided not to progress with Cetraxal.

An application has been received from James Rainsbury, consultant ENT surgeon from Plymouth to consider the inclusion of Cilodex ear drops suspension be added to the formulary for use in S&W Devon. The applicant has proposed that Cilodex ear drops be added as a green, first line, drug for the management of AOE and also for the management of AOMT in line with the product licence.

The NICE Clinical Knowledge Summary (CKS) states that there is no evidence to suggest which topical antibacterial product is more effective for AOE, so factors such as the person's preference, risk of adverse effects, cost, dosing frequency, and status of the eardrum should be taken into account.

It was noted that the figure for the annualised quantity dispensed for Gentamicin 0.3% with hydrocortisone 1% (10ml) should read 4,356 in the meeting paper rather than the 17,424 stated.

The FIG considered and accepted the proposed formulary entry for Cilodex (ciprofloxacin 3mg/ml & dexamethasone 1mg/ml) ear drops, suspension.

The FIG accepted the proposed formulary entry for anti-infective preparations for the management of AOE and AOMT including the addition of Cilodex® (ciprofloxacin 3mg/ml & dexamethasone 1mg/ml) ear drops suspension with minor amendment:

- It was agreed that the entry for ciprofloxacin 0.3%, dexamethasone 0.1% (Cilodex) appear above the entry for clioquinol 1% flumetasone 0.02%.
- ACTION: Formulary team to add the accepted formulary entry for anti-infective preparations for the management of AOE and AOMT including the addition of Cilodex (ciprofloxacin 3mg/ml & dexamethasone 1mg/ml) ear drops, suspension to the formulary in line with the discussion.

It was also agreed that the Formulary team contact the Antimicrobial Stewardship Group regarding any known microbial resistance to aural ciprofloxacin versus other antimicrobial agents.

ACTION: Formulary team to contact the Antimicrobial Stewardship Group regarding any known microbial resistance to aural ciprofloxacin versus other antimicrobial agents.

5. Consideration of removal of branded Cholurso® (ursodeoxycholic acid 250mg) tablets

Ursodeoxycholic acid 250mg tablets are listed in the formulary with a preferred brand of Cholurso. There is no preferred brand currently assigned to the suspension or 150mg and 300mg tablets. The preferred brand was added for use in South and West Devon in March 2017. The Medicines Optimisation teams have now requested that removal of the brand be considered by the FIG as branded prescribing no longer offers a financial advantage for this item. Ursodeoxycholic acid 250mg tablets are listed as category C in the drug tariff; Cholurso is listed as the proprietary reference product (January 2019 Drug Tariff online).

The FIG considered and accepted the proposal to remove Cholurso as the preferred brand of ursodeoxycholic acid 250mg tablets.

ACTION: Formulary team to remove Cholurso as the preferred brand of ursodeoxycholic acid 250mg tables.

ACTION: Formulary team to remove Cholurso from the preferred brand page of the formulary.

6. Emollient product review

Formulary emollient recommendations have been considered as part of the rolling review programme.

NICE Clinical Guideline CG57 (Atopic eczema in under 12s: diagnosis and management) (NICE, 2007) reports a lack of studies that evaluated the effectiveness of emollients in children with atopic eczema. The authors of a recent Cochrane systematic review of emollients and moisturisers for eczema report that most moisturisers provided some benefit and that when combined with active treatment greater benefit was seen than with active treatment alone.

Discussions had taken place with specialists across Devon to allow clear locally agreed guidance and a reduced list of recommended products. Local specialists had agreed that a pragmatic approach be taken to the selection of recommended products.

The FIG discussed and accepted the prosed formulary entry subject to minor amendment:

13.2.1 Emollients:

- There was discussion about self-care for people without a diagnosis or with self-limiting conditions and over-the counter products.
- It was noted that there was a time cost for GPs associated with changing patients from one product to another.
- There was discussion about the shelf-life of products once opened. Lily Hammarlund-Sim to forward information to the Formulary team from the Care Quality Commission (CQC) relating to expiry dates.
- It was agreed to add the following note to the guidance 'For most types of emollient, several products have been included to allow for patients to try a number of options, before clinicians consider non-formulary options'.

ACTION: Lily Hammarlund-Sim to forward information on the shelf-life of opened products to the Formulary team.

ACTION: Formulary team to check what the CCGs say about open pots.

- Gels
 - Adex[®] Gel agreed not to add as the proposed benefit is not well established and the additional cost cannot be justified.
 - Remove Doublebase Dayleve[®] as the proposed benefit is not well established and the additional cost cannot be justified.
- Creams Hydromol agreed not to add as the proposed benefit is not well established and the additional cost cannot be justified.
- Bath and shower preparations
 - Bath and shower preparations remove Dermalo[®] bath emollients and Doublebase[®] shower gel. The FIG felt that the evidence did not warrant the inclusion of these products in the formulary. Forthcoming NHS England guidance is expected to support this and will be added to the formulary once published.
- Products for specific clinical conditions:

Antimicrobials – add not suitable for prolonged use; one-month maximum usage.

• Bath and shower emollients – remove Dermol[®]200 and Dermol[®] 600.

ACTION: Formulary entry for Emollients to be updated in line with the discussion.

The FIG thanked the Formulary team for their work in producing this guidance and suggested that prescribing data be reviewed in the future to ascertain the levels of savings made.

Sarah Marner left the meeting during this discussion.

7. NHS England conditions for which OTC items should not be routinely prescribed in primary car

In March 2018, following public consultation NHS England (NHSE) and NHS Clinical Commissioners (NHSCC) published guidance for CCGs, on conditions for which over the counter (OTC) items should not routinely be prescribed in primary care. This guidance relates to 35 conditions, which these organisations have identified as areas which are either 'self-limiting' or where self-care may be more appropriate, plus probiotics and vitamins and minerals.

Both CCGs in Devon also conducted a local engagement exercise with clinicians and patient groups and fed this in to the national consultation. The commissioning guidance was considered by both CCGs in Devon, and they decided to implement the guidance in full.

The Formulary Team was asked to include the wording agreed by both CCGs into the formulary.

The FIG considered and agreed the proposed formulary entry subject to clarification being sought from Oksana Riley, MO Pharmacist, NEW Devon CCG on the meaning of bullet point 'Patients on prescription only medication' listed in the 'Exceptions to the guidance'.

- ACTION: Formulary Team to seek clarification from Oksana Riley on the meaning of bullet point 'Patients on prescription only medication' listed in the 'Exceptions to the guidance'.
- ACTION: Formulary Team to update the formulary in line with the guidance.

A query was raised as to whether there will be an educational programme for patients. It was noted that the Local Pharmaceutical Committee had not been asked to support this. There was also discussion about the need to ensure GPs and pharmacies are joined up to ensure that patients are not sent by GPs to pharmacies and back to their GP by pharmacies. It was noted that Oksana Riley is producing a leaflet for GPs explaining which products can be given to different patient groups. It was suggested that lain Roberts contact Oksana if more information is needed.

Tom Kallis left the meeting after this discussion.

8. Unipolar depression guidance review (update)

The Devon Formulary Team have worked to update the unipolar depression formulary guidance. NICE clinical guidelines and Devon Partnership NHS Trust (DPT) prescribing guidelines have been used to update the guidance. It is intended that the revision becomes Devon wide guidance; currently the guidance North and East Devon differs from that for South and West Devon the aim is to align and update the content. The current formulary antidepressant entries are also subject to update.

The guidance was originally considered by the South and West Devon Formulary Interface Group (FIG) in November 2018; a number of changes were suggested and the guidance has since been updated to reflect the discussions at the meeting. Subsequently the guidance has also been discussed by the North and East Devon FIG and further updates have been made following the meeting, including the addition of guidance relating to drugs that prolong the QT interval.

The FIG discussed the proposed formulary entry. In particular there was discussion about:

• Augmentation strategies/combinations

It was agreed that the Formulary team discuss this section with DPT. A discussion may be required at a Clinical Policy Committee meeting. It was agreed that the Formulary team would update the FIG electronically subsequent to the discussion with DPT.

ACTION: Formulary team to update the FIG electronically following discussion with DPT.

- <u>Cardiovascular</u>
 - Drugs that prolong the QT interval it was noted that the information included in the proposed formulary entry is taken from the current paper version of the British National Formulary (BNF). It was proposed that the formulary depression guidance will link to the guidance on drugs that prolong the QT interval. It was noted that the Formulary team would have to monitor the paper BNF for new additions.

ACTION: Formulary team to update the formulary entry for depression and associated drugs in line with the discussion.

ACTION: Formulary Team to add new guidance on drugs that prolong the QT interval to the formulary.

9. Management of Gout

Formulary guidance for the management of gout has been considered as part of the rolling review process. It is proposed to align the North and East Devon Guidance and South and West Devon Guidance to provide easily accessible information to primary care prescribers.

The proposed formulary entry has been developed and updated using NICE Clinical Knowledge Summary (CKS) (2018): Gout the British Society for Rheumatology (BSR) guideline for the management of gout (2017) and EULAR management guidelines for Gout (2016).

The FIG discussed and accepted the proposed formulary guidance for the management of gout with minor amendment:

- Treatment of acute gout
 - Indometacin Change colour status from 'green' first line to 'blue'. Remove indication for acute gout and include other licenced indications.
 - Pharmacological management
 - Ibuprofen amend dose to include maximum dose.
 - Add 'short term' to 'Consider prescribing a proton pump inhibitor (PPI) for gastric protection'.
 - Link to prescribing non-steroidal anti-inflammatory drugs formulary page for prescribing guidance relating to NSAIDS e.g. PPI prescribing.
 - Prednisolone add dose 20-30 mg for 5 days.

ACTION: Formulary team to update the formulary entry in line with the discussion.

10. Lyme Disease guidance (update)

The current formulary guidance has been revised in line with the NICE Guideline NG95, published in April 2018. The proposed draft was previously considered by the South and West FIG in autumn 2018 when a number of points were raised about prescribing of doxycycline which although recommended by NICE for children aged 9-12 with a single lesion is contra-indicated in the UK for children under 12. Feedback received from a paediatrician and microbiologist in S&W Devon had indicated a reluctance to routinely recommend doxycycline in primary care, and a preference for amoxicillin first line in this situation (NICE recommend amoxicillin as first line alternative). The S&W FIG decided to recommend amoxicillin, first line with azithromycin as an alternative (on specialist recommendation) for these patients.

The Formulary team were also asked by S&W FIG to clarify the rational provided by NICE for recommending IV ceftriaxone rather than oral doxycycline for patients with Lyme disease with focal symptoms affecting the central nervous system. This was considered and accepted by via e-FIG, however it was suggested that these patients would require administration of medicine via secondary care services. Wording to reflect this was discussed with Phil Melluish and Paul Humphriss and is included in the revised draft guidance.

This guidance was recently considered by the N&E FIG, prior to which additional consultation on the use of doxycycline in children aged 9-12 years was undertaken. The N&E FIG agreed to adopt the NICE recommendation for use of doxycycline in a contraindicated population, as long as this status was clearly documented in the guidance.

The S&W FIG were asked to consider whether the new draft guidance was clear, whether the new draft wording regarding outpatient or home parenteral antibiotic therapy services was acceptable and whether the FIG was happy that the S&W Devon guidance differed from the N&E Devon guidance on recommendations on use of doxycycline for children aged 9-12 years.

The FIG considered and accepted the proposed formulary entry with minor amendment. It was noted that there was no evidence of improved efficacy of doxycycline compared to alternative treatments in children and that it was limited in adults. It was also noted that if GPs prescribe doxycycline when requested by specialists, the GP accepts the risk.

ACTION: Formulary team to add S&W Devon guidance for Lyme disease guidance to the formulary in line with the discussion.

11. Palliative care opioid tables (update)

The Formulary team has been liaising with Dr Human, Consultant in Palliative Care regarding the Palliative Care Opioid Equivalence Table. The table is now complete with relevant notes included. The local hospices will own the document and it will be published on the Hospice websites. The formulary website will include a link to the Hospice websites and the resource.

Currently a slightly different version of the table is in use in North and East Devon. The Formulary team will work with teams in North and East Devon with the aim of using the same document across Devon.

The Formulary team will note the update on the recent drug decisions document and e-mail Secondary Care Pharmacists.

- ACTION: Formulary team to note the addition of the Palliative Care Opioid Equivalency Table on the recent drug decisions document.
- ACTION: Formulary team to e-mail Secondary Care Pharmacists about the Palliative Care Opioid Equivalency Table update.

12. Recent drug decisions (including NICE)

The recent drug updates were noted.

13. MHRA Drug Safety Updates: Nov '18 & Dec '18

November 2018

- Hydrochlorothiazide: risk of non-melanoma skin cancer, particularly in long-term use. This is not included in the formulary. It was agreed that no action was required.
- Systemic and inhaled fluoroquinolones: small increased risk of aortic aneurysm and dissection; advice for prescribing in high-risk patients. Add notes to main quinolone drug page; also note on relevant guidance pages when quinoline is recommended:
 - systemic (by mouth or injection) and inhaled fluoroquinolones may be associated with a small increased risk of aortic aneurysm and dissection, particularly in older patients

- fluoroquinolones should only be used after careful benefit-risk assessment and after consideration of other therapeutic options in patients at risk for aortic aneurysm and dissection
- Conditions predisposing to aortic aneurysm and dissection include:
 - a family history of aneurysm disease
 - diagnosis with pre-existing aortic aneurysm and/or aortic dissection
 - other risk factors or conditions predisposing for aortic aneurysm and dissection (for example, Marfan's syndrome, Ehlers-Danlos syndrome, Takayasu arteritis, giant cell arteritis, Behcet's disease, hypertension, and known atherosclerosis)
- advise patients, particularly elderly people and those at risk, about rare events of aortic aneurysm and dissection and of the importance of seeking immediate medical attention in case of sudden-onset severe abdominal, chest or back pain
- Sildenafil (Revatio and Viagra): reports of persistent pulmonary hypertension of the newborn (PPHN) following in-utero exposure in a clinical trial on intrauterine growth restriction. It was agreed that no action was required.
- Support Yellow Card: improve the safety of medicines in pregnancy and breastfeeding, and in babies and children. It was agreed that no action was required.

ACTION: Formulary team to add agreed information from the November 2018 MHRA Drug Safety Update to the formulary.

December 2018

- Oral lidocaine-containing products for infant teething: only to be available under the supervision of a pharmacist. This is not included in the formulary. It was agreed that no action was required.
- Valproate medicines: are you in acting in compliance with the pregnancy prevention measures? All the points raised have already been covered in the formulary. It was noted that practice pharmacists may be able to help identify relevant patients.
- Emollients: new information about risk of severe and fatal burns with paraffin-containing and paraffin-free emollients. It was agreed that this advice will be included in the formulary as discussed in the emollient guidance update.
- Direct-acting antivirals for chronic hepatitis C: risk of hypoglycaemia in patients with diabetes. Add headline and brief summary of the advice together with a link to the update to the hepatitis C drug page.
- Hydrocortisone muco-adhesive buccal tablets: should not be used off-label for adrenal insufficiency in children due to serious risks. Add headline and link out to advice.

ACTION: Formulary team to add agreed information from the December 2018 MHRA drug safety update to the formulary.

14. Any other business

Venue for next meeting

It was noted that the meeting due to take place on Wednesday 13 March will be held at Future Inn, Plymouth.

International Normalised Ratio (INR) Test Strips

A query was raised with regard to INR Test Strips and anticoagulation. The discussion included:

- Purchasing of test strips for patients to self-monitor and the intervals at which testing should be undertaken.
- Prescribing of NOACs if patients decline Warfarin.

	Action	Lead	Status
19/01	Matters arising: Title of Chapter 8 – Malignant disease to be amended in line with the discussion.	Formulary team	Outstanding
19/02	Hydroxychloroquine for rheumatological and dermatological conditions: LMC and specialists to be asked for their views. Draft guidance to be brought back to FIG together with the outcome from the forthcoming CPC meeting.	Formulary team	Outstanding
19/03	Formulary entry for anti-infective preparations for the management of AOE and AOMT including the addition of Cilodex (ciprofloxacin 3mg/ml & dexamethasone 1mg/ml) ear drops, suspension to the formulary in line with the discussion.	Formulary team	Outstanding
19/04	Antimicrobial Stewardship Group to be contacted regarding any known microbial resistance to Cilodex® (ciprofloxacin 3mg/ml & dexamethasone 1mg/ml) ear drops, suspension	Formulary team	Complete
19/05	Remove Cholurso as the preferred brand of ursodeoxycholic acid 250mg tables.	Formulary team	Complete
19/06	Remove Cholurso from the preferred brand page of the formulary	Formulary team	Complete
19/07	Emollients – information on the shelf-life of opened products to be forwarded to the formulary team.	Lily Hammarlund- Sim	Complete
19/08	Emollients – check what the CCGs say about open pots.	Formulary team	Complete
19/09	Formulary entry for emollients to be updated in line with the discussion	Formulary team	Complete
19/10	NHS England conditions for which OTC items should not be routinely prescribed in primary care: Clarification to be sought from Oksana Riley on the meaning of bullet point 'Patients on prescription only medication' listed in the 'Exceptions to the guidance'.	Formulary team	Outstanding
19/11	NHS England conditions for which OTC items should not be routinely prescribed in primary care: update the formulary in line with the guidance.	Formulary team	Outstanding
19/12	Unipolar depression guidance review (update): Update FIG electronically following discussion with DPT.	Formulary team	Complete
19/13	Update the formulary entry for depression and associated drugs in line with the discussion.	Formulary team	Outstanding
19/14	Add new guidance on drugs that prolong the QT interval to the formulary.	Formulary team	Outstanding
19/15	Management of gout: Formulary entry to be updated in line with the discussion.	Formulary team	Outstanding
19/16	S&W Devon guidance for Lyme disease to be added to the formulary in line with the discussion.	Formulary team	Complete
19/17	Palliative care opioid tables (update): note addition of the palliative care opioid equivalency table on the recent drug decisions document.	Formulary team	Complete

19/18	Palliative care opioid tables (update): E-mail Secondary Care Pharmacists about the Palliative Care Table.	Formulary team	Complete
19/19	Agreed information from the November 2018 MHRA Drug Safety Update to be added to the Formulary.	Formulary team	Outstanding
19/20	Agreed information from the December 2018 MHRA Drug Safety Update to be added to the Formulary.	Formulary team	Outstanding