Meeting of the South and West Devon Formulary Interface Group

Minutes

Wednesday 11 December 2019: 2:00 pm – 4.30 pm

The Watermark, Erme Court, Leonards Road, Ivybridge PL21 0SZ

Present:

Andrew Gunatilleke (Chair)	Consultant	Torbay and South Devon NHS FT
Andy Craig	GP	NHS Devon CCG
Matt Howard	Clinical Evidence Manager	NHS Devon CCG
Phil Melluish	GP	NHS Devon CCG
Marco Motta	Pharmaceutical Advisor	NHS Kernow CCG
Hilary Pearce	Clinical Effectiveness Pharmacist	NHS Devon CCG
Tony Perkins	Senior MO Pharmacist	NHS Devon CCG
Darren Wright	Joint Formularies Technician	NHS Devon CCG

In attendance:

Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NHS Devon CCG

1. Welcome and announcements

Apologies

Trudy Bown	Chief Pharmacy Procurement and IT Manager	University Hospitals Plymouth NHS Trust
Heidi Campbell	Pharmacy Advisor	Kernow CCG
Demelza Grimes	Medicines Optimisation Pharmacist (South)	NHS Devon CCG
Bill Nolan	GP	NHS Devon CCG
Amy Rice	Advanced Specialist Clinical Pharmacist	Livewell Southwest
Peter Rowe	Consultant Nephrologist	University Hospitals Plymouth NHS Trust
Christopher Sullivan	Pharmacist	Devon Partnership NHS rust

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
Loteprednol etabonate 0.5% (Lotemax®) for the treatment of steroid responsive inflammatory conditions of the eye	Bausch & Lomb UK Ltd
Alternative treatments:	
Prednisolone acetate 1% eye drops (Pred Forte®)	Allergan Ltd
Fluorometholone 0.1% eye drops (FML Liquifilm®)	Allergan Ltd
Other corticosteroid eye drops	Various manufacturers
Consideration of the inclusion of Budesonide 2mg/dose rectal foam	Dr. Falk Pharma UK Ltd
Consideration of UCS Debridement for addition to the formulary	Medi UK Ltd
Other debridement pads: Debrisoft® Pad	L&R Medical UK Ltd, formally known as Activa Healthcare Ltd
Ondansetron for nausea and vomiting in pregnancy: new safety information	N/A – new safety information
Consideration of One-Alpha for addition as a preferred brand	Leo Laboratories
Alternatives: generic products	Various manufacturers
Valupak colecalciferol tablets 1000u	BR Pharmaceuticals Ltd
Alternatives: Stexerol® D3 tablets 1000u	Koya Kirin Ltd
Other colecalciferol 800u and 1000u tablets	Various manufacturers
COPD guidance review	
Various medications	Various manufacturers
Pneumonia guidance review: antimicrobial guidance (NICE)	
Various medications	Various manufacturers
Cough (acute) guidance review: antimicrobial guidance (NICE)	

Various medications	Various manufacturers
Chapter 14. Vaccines guidance review Various vaccinations	 Various medications
Lidocaine Plasters (Ralvo®)	Grunenthal Ltd

Items discussed by e-FIG

e-FIG Item	Company
SMS: Dapsone for the treatment of dermatitis herpetiformis and other dermatoses in adults	Various manufacturers
Effective contraception and frequency of pregnancy testing when medicines with teratogenic potential are prescribed	N/A – new safety information

Name	Declaration
Tony Perkins	As previously declared was part of 2019 NICE COPD committee – group no longer meeting as guideline published.

2. Minutes of the meeting held on Wednesday 9th October 2019 and matters arising

The minutes of the meeting held on Wednesday 9th October 2019 were approved.

Summary of actions

	Action	Lead	Status
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.* *The Clinical Effectiveness team is working with providers on identifying patients who may be at risk of hydroxychloroquine retinopathy and where such patients should be referred for testing, who will do this and how it will be resourced.*		

	It was noted that the risk for patients of getting hydroxychloroquine retinopathy is low. The Formulary Team is also looking at the prescribing guidance. Draft SMS Guidance will be brought to a future FIG meeting.	Formulary team	Outstanding
19/28	*Formulary entry for Urinary Tract Infections to be updated in line with the discussion.* *The Formulary team is awaiting additional guidance from microbiologists.* *Comments have been received from Jim Greig. Steve Cooke is taking this forward.* Work is in progress.	Formulary team	Outstanding
19/29	*Urinary tract infections - Slider for people over the age of 65 to be brought to a future meeting.* *Further queries had been received from Jim Greig. The Formulary Team will raise with Steve Cooke.* Work is in progress.	Formulary team	Outstanding
19/43	*Continence formulary guidance – undertake further work in line with the discussion to rationalise and reduce the number of products available.* Drafts have been sent for comments to specialists, with responses to be brought back to FIG.		Complete
19/81	Accepted formulary entry for Kelhale to be added to the formulary.		Complete
19/82	Accepted formulary entry for Gluco Rx Carepoint – Ultra pen needles to be added to the formulary.		Complete
19/83	*Accepted formulary entry for Dermisplus prevent pads to be added to the formulary.* This will be included in Chapter 17 - Wound Management.	Formulary team	Outstanding
19/84	Accepted formulary entry for latanoprost 50mcg / timolol 5mg/ml preservative free eye drops to be added to the formulary.		Complete
19/85	Estriol 0.01% cream to be removed from the formulary.		Complete
19/86	Add the accepted entry for glycopyrronium bromide oral solution for the treatment of severe sialorrhoea in children and adolescents aged 3 years and older to the formulary.		Complete
19/87	Add the accepted formulary entry for Continuous Glucose Monitoring to the formulary.		Complete

19/88	Amend guideline for Dapsone for the treatment of dermatitis herpetiformis and other dermatoses in adults in line with the discussion and circulate via the e-FIG process for agreement.		Complete
19/89	*Add accepted formulary entry for UrgoClean Ag Dressing to the formulary.* This will be included in Chapter 17 – Wound Management.	Formulary team	Outstanding
19/90	COPD review – any additional thoughts on the draft guidance to be forward to the Formulary team.		Complete
19/91	Formulary entry for chlamydia to be updated in line with the discussion.		Complete
19/92	Specialists to be asked to provide evidence for reduction of risk of bacterial infection with VaPro Plus.		Complete
19/93	Formulary entry for continence to be updated in line with the discussion.		Complete
19/94	Wound management review – ascertain whether a similar process for supply of dressings exists in Devon. Status of action to be followed up.	Demelza Grimes Formulary team	Outstanding Outstanding
19/95	MHRA Drug Safety Update – July: Febuxostat (Adenuric) – add a reference to this on the guidance page.		Complete
19/96	MHRA Drug Safety Updates – July: Tocilizumab (RoActemra) – add title and link out to advice for healthcare professionals.		Complete
19/97	MHRA Drug Safety Updates – August: Daratumumab (Darzalex▼): risk of reactivation of hepatitis B virus – add title and link out to the advice for healthcare professionals.		Complete
19/98	MHRA Drug Safety Updates – September: Hormone replacement therapy: add title and link out to advice for healthcare professionals.		Complete
19/99	MHRA Drug Safety Updates - September: Fingolimod (Gilenya ▼) – add title and link out to advice for healthcare professionals.		Complete
19/100	MHRA Drug Safety Updates – September: Elmiron (pentosan polysulfate sodium) advice to be added to the formulary when NICE TA 610 is added	Formulary team	Outstanding
19/101	MHRA Drug Safety Updates – September: Montelkast (Singulair) – add summary of advice to the product page.		Complete

Matters Arising

Report of e-FIG decisions: October and November 2019

October 2019

One item was considered in October

Devon Wide SMS (Specialist Medicines Service) for Dapsone. Responses received indicated acceptance of the proposal.

The formulary has been updated.

November 2019

Formulary guidance for effective contraception and frequency of pregnancy testing when medicines with teratogenic potential are prescribed. Responses received indicated acceptance of the proposed formulary entry. The formulary will be updated.

ACTION: Formulary team to update the formulary guidance for effective contraception and frequency of pregnancy testing when medicines with teratogenic potential are prescribed.

3. Loteprednol for the treatment of steroid responsive inflammatory eye conditions

The routine commissioning of loteprednol (Lotemax®) was recommended by the Clinical Commissioning Group's Clinical Policy Committee at its meeting on 20th November 2019. Loteprednol is accepted in Devon for the treatment of steroid responsive inflammatory eye conditions in patients who have a known clinically significant rise in intraocular pressure with other steroid eye drops. Loteprednol does not have a UK product licence for the treatment of steroid responsive inflammatory eye conditions and the patient must be made fully aware of the unlicensed nature of the treatment and the rationale for its proposed use.

Patients with inflammatory eye conditions such as uveitis and vernal keratoconjunctivitis often require long term or frequent courses of steroid eye drops.

Prolonged use of steroid eye drops may cause an increase in intraocular pressure (IOP) in some patients. In patients who have experienced clinically significant rises in IOP on first line steroid treatment, loteprednol offers an alternative which may result in a lower rise in IOP in some individuals and permit continued treatment with topical steroid drops. Loteprednol is not commissioned as a first line option as the evidence that it has a meaningfully lower incidence of raised IOP is of poor quality and loteprednol is more expensive than alternative first line options.

The FIG considered and accepted the draft formulary entry for loteprednol subject to the completion of the CCG's governance procedures.

There was discussion about the colour status of loteprednol in the formulary. It was agreed that this would be 'red', hospital only since ongoing use requires IOP monitoring by specialists.

ACTION: On completion of the CCG's governance procedures Formulary team to add the accepted formulary entry for loteprednol for the treatment of steroid responsive inflammatory eye conditions to the formulary.

4. Consideration of the inclusion of Budesonide 2mg/dose rectal foam

An application for the addition of budesonide rectal foam has been received from Dr Alan Desmond, IBD clinical lead at Torbay and South Devon NHS Foundation Trust and Larissa Sullivan, Interface Pharmacist, Torbay and South Devon NHS Foundation Trust.

Budesonide (Budenofalk®) 2mg/dose rectal foam is licenced for the induction of remission of active ulcerative colitis that is limited to the rectum and the sigmoid colon in adults aged > 18 years. It is intended to be used as a second line alternative to hydrocortisone rectal foam as per North and East Formulary. It is suggested that budesonide is given 'amber' status in line with other rectal corticosteroids

The addition of budesonide has been requested as hydrocortisone rectal foam has been unavailable for 12 months. Budesonide rectal foam is less expensive than prednisolone rectal foam (the only other alternative for patients requiring corticosteroid rectal foam).

Application for licensing shows that budesonide rectal foam is non-inferior to hydrocortisone rectal foam and non-inferior to budesonide rectal enema

The supply of budesonide rectal foam by Torbay Hospital pharmacy and the increase in primary care expenditure if GPs were asked to prescribe was outlined.

FIG was asked if they approve the application, and the revised formulary entry. This will be a decision in principle until the applicants each provide a DoI which will be forwarded to the chair.

There was discussion about:

- The extent to which rectal enemas are used compared to rectal foam.
- The choice of products and patient preference.

The FIG considered and accepted the proposed formulary entry without amendment.

ACTION: Formulary team to update the formulary with the accepted formulary entry subject to receipt of a DoI from the applicants.

5. Consideration of UCS Debridement for addition to the formulary

UCS Debridement is a sterile, pre-moistened debridement cloth, containing aloe vera, allantoin, and poloxamer (a wetting agent), that can be used to clean wounds, remove dead skin cells, as well as moisturise the surrounding area. It is recommended for use on chronic

and acute wounds, first- or second-degree burns, and all types of ulcers; including pressure ulcers.

Tissue viability nurse teams in South and West Devon have suggested they would like to use UCS Debridement as a first line option to mechanically debride wounds of slough and biofilms to promote a prepared wound bed for healing with standard or advanced therapies, in place of current formulary physical debridement options. Podiatrists in South and West Devon have requested that Debrisoft® Pad remains a formulary option for diabetic foot ulcers.

The proposed amendment to the formulary is for UCS debridement to replace Debrisoft Pad as a first line option and Debrisoft to be reclassified to an amber (specialist) product for diabetic foot ulcers.

The FIG considered and accepted the proposed formulary entry for physical debridement pads without amendment. There was discussion about:

- The evidence for UCS Debridement rather than gauze. The Formulary team noted that evidence is often unclear. However, this product is cheaper than some options.
- The potential benefits for patients. It is suggested that these cloths pick up debris and clean wounds with minimal pain and bleeding for patients.
- A Formulary team member will be meeting the Tissue Viability Teams in January 2020. It will be suggested that Podiatry Teams be asked to undertake a trial of UCS Debridement due to the cost differential.

ACTION: Formulary team to add the accepted formulary entry for Physical debridement pads to the formulary.

6. Ondansetron for nausea and vomiting in pregnancy: new safety information

The European Medicines Agency (EMA) has recommended the Summary of Product Characteristics (SPCs) for ondansetron products are updated to indicate that ondansetron should not be used during the first trimester of pregnancy. This recommendation is the result of a review of studies of pregnancy outcomes by the EMA Pharmacovigilance Risk Assessment Committee (PRAC) which identified a small increase in the risk of orofacial cleft following the use of ondansetron during pregnancy.

The Devon formularies include a section on nausea and vomiting in pregnancy and hyperemesis gravidarum which was developed in line with the Green Top guidance issued by the Royal College of Obstetricians and Gynaecologists (RCOG). The RCOG recommend that ondansetron is considered after the use of antihistamines, phenothiazines and dopamine antagonists, and that ondansetron should preferably not be used during the first trimester of pregnancy.

The RCOG has not updated its guidance for ondansetron in light of the recommendation from the EMA. The UK Teratology Service (UKTIS) has issued a response to the EMA's recommendation. UKTIS and European Network of Teratology Services (ENTIS) support the place in therapy for ondansetron recommended by the RCOG.

The draft formulary update for ondansetron use in pregnancy incorporates risk for orofacial cleft following ondansetron use in pregnancy and UKTIS advice that women should be counselled on the benefits of ondansetron and the increase in risk of orofacial cleft.

The specialists who have responded consider the wording to be appropriate.

- There was discussion about the evidence relating to the slightly increased risk of orofacial cleft in babies following use of ondansetron during the first trimester of pregnancy.
- Treatment of nausea and vomiting during pregnancy is an off-label use of ondansetron. The Formulary team will check whether the other formulary options for nausea and vomiting in pregnancy are specifically licensed for this indication.

ACTION: Formulary team to check whether other antiemetic drugs included in the formulary section on the treatment of nausea and vomiting in pregnancy and hyperemesis gravidarum are licensed for this indication.

The FIG accepted the formulary entry without amendment.

ACTION: Formulary team to update the formulary guidance for ondansetron with the approved wording.

7. Consideration of One-Alpha for addition as a preferred brand

Alfacalcidol capsules are included in the Devon Formulary for vitamin D supplementation in severe renal impairment. One-Alpha is the originator brand of alfacalcidol capsules – available as 250 nanograms, 500 nanograms and 1 microgram capsules. The CCG Medicines Optimisation Team has requested the inclusion of One-Alpha capsules in the formulary as a preferred brand for alfacalcidol capsules which are specialist (amber) drugs in the North and East Formulary and the South and West Formulary. All strengths of One-Alpha capsules are less expensive than generic alfacalcidol capsules.

Responses from specialists indicated they would be happy for One-Alpha to be the preferred brand and for the switch initiative in primary care.

At the time of writing the paper, one wholesaler was out of stock of the 250 nanogram and 500 nanogram capsules which account for 80% of prescribing so the FIG was asked to make a decision at the meeting, however the formulary will not be updated until the stock situation is resolved.

The FIG considered and accepted the proposed formulary entry without amendment.

ACTION: Formulary team to update the formulary with the accepted formulary entry for One-Alpha as the preferred brand of alfacalcidol when all strengths of capsules are available at wholesalers.

8. Valupak colecalciferol tablets

Colecalciferol tablets are included in the formulary as the preferred brand Stexerol D3. The 25,000 units (625 microgram) tablet and the 1,000 units (25 microgram) tablet are formulary options.

The FIG had an initial discussion of a request from the CCG Medicines Optimisation team for the addition of Valupak as an additional preferred brand option for colecalciferol 1,000 units tablets and to switch prescribing of colecalciferol 800 units/day to colecalciferol 1000 units/day. Eight hundred unit capsules and tablets are not formulary options. The 25,000 units tablet will remain unchanged. Valupak tablets are a food supplement.

Valupak tablets are substantially less expensive than Stexerol D3 tablets. The cost of 28 days supply of Valupak 1,000 units tablets is £0.28 compared with £2.95 if Stexerol D3 is prescribed.

An initial consultation with specialists is ongoing.

The FIG considered the proposed formulary entry.

The discussion included:

- Whether the FIG was happy for the food supplement Valupak to be included in the formulary as an additional preferred brand. GPs present were in agreement with the use of Valupak.
- That the Formulary team had received replies from most specialities indicating support from most specialists in North and East Devon. The renal specialist had yet to be contacted. No response from specialists in South and West Devon indicating support at the time of the meeting. Views are being sought from FIG members.
- The different patient groups who may be prescribed Valupak and appropriate doses for each. The consultation with specialists identified two groups of patients who the specialists considered should not have their daily doses of colecalciferol switched from 800 units/day to 1,000 units/day. The proposed formulary entry highlights this. It was noted that patients who have undergone bariatric surgery may not be easily identified. If the MO team decide to proceed with this proposal, further exploration of this point may be required.
- GPs present suggested that most patients would know if their dose had changed and would query the change.

9. COPD guidance review

Work has been underway to update the Devon formulary COPD guidance which is currently based on guidance produced by GOLD (2017). Since the guidance was last reviewed, national and international guidelines have been updated; the 2019 GOLD Report is now available alongside the 2018 publication of NICE Guideline 115 (updated 2019).

Consultation earlier this year with Devon wide respiratory consultants and Formulary Interface Group (FIG) members, including GP representatives, identified a consensus in opinion

towards a revision of the formulary guidance in line with the 2019 GOLD Report. The first draft of this guidance was considered by the N&E Devon FIG in September 2019, and by the S&W Devon FIG in October 2019.

A second draft of the proposed formulary guidance was drafted which reflected the output of the two prior FIG meetings, this was circulated to specialists for further comment.

Considering the environmental impact of inhalers specialists responses indicated broad support for the proposal to recommend DPI or SMI over pMDI or BAI, where clinically appropriate, although specific comments highlighted the need to consider the impact on salbutamol, that some patients may continue to need pMDI, and that a mixture of inhaler device types should be avoided for individual patients.

Specialists responses indicated support for a switch of salmeterol to second line LABA, with both formoterol and indacaterol as first line options instead.

There were mixed responses regarding treatment recommendations for patients with persistent breathlessness or exercise limitation despite LABA plus LAMA combination inhaler. The N&E Devon FIG considered these specialist comments and decided to include recommendations from both NICE and GOLD, reworded and with expanded notes to aid GP decision making.

In addition, the Antistatic Space Chamber Plus, a valved holding chamber (VHC) was considered and accepted for inclusion. In 2018 the N&E Devon FIG had accepted inclusion of this device, noting the paucity of evidence that one VHC is clinically superior to another and concluding that it would seem reasonable that consideration of inclusion be primarily based on acquisition cost. This device is available at a lower acquisition cost than the other Devon Formulary recommended medium-volume spacer device (Aerochamber Plus).

The FIG was asked to consider and accepted the final draft of the COPD formulary guidance with minor amendments:

- Reclassification of Onbrez® Breezhaler® to blue (second line)
- Recommended inhaled treatment: change ‘consider’ to ‘offer’ in initial inhaled therapy – Group D
- Relvar®Ellipta®92/22 fluticasone furoate / vilanterol DPI to be placed as the first ICS plus LABA combination inhaler. Note in the formulary that this is the cheapest product.
- 3.4.1 Combination Inhalers
  - Seretide®Accuhaler® There was discussion regarding the colour status of this product.
  - AirFluSal® MDI The FIG was asked whether Seretide Evohaler 125 and 250 should be added for adolescents? It was agreed not to add this. The Formulary Team will go back to Larissa Sullivan.
- 3.7 Mucolytics
  - Carbocisteine remove oral liquid 250mg/5ml.

Formulary Team to amend the formulary guidance for COPD in line with the discussion.

ACTION: Formulary Team to amend the formulary guidance for COPD in line with the discussion.

10. Pneumonia guidance review: antimicrobial guidance (NICE)

NICE in conjunction with Public Health England issued updated guidance for antimicrobial prescribing for community-acquired pneumonia (CAP) (NG138) in September 2019. This gives a short timeline in which to update the formulary guidance before the winter season.

The existing NICE clinical guideline Pneumonia: Diagnosis and Management (CG191) remains in place but has been updated to remove sections on antibiotic therapy. The diagnostic criteria are unchanged. However, the new guideline also includes additional recommendations on subjects covered by the existing clinical guideline.

The key changes proposed for the formulary guidance from NG138 are:

- Time to initiation of treatment: NG138 has timelines for initiation of treatment whereas the clinical guideline did not have a recommendation on this. Local guidance recommends immediate treatment.
- Treatment of low severity CAP: Additional antibiotic options recommended if penicillin-allergy and if amoxicillin is unsuitable (atypical pathogens suspected)
- Moderate severity CAP managed in the community: the existing antibiotic options differ between North and East Devon and South and West Devon. NG138 recommends dual therapy only if atypical pathogens are suspected.
- Microbiological tests: No routine tests for low severity CAP. Recommendations given for moderate or high severity CAP.

It was noted that the two Devon regions currently differ in their recommendations for CAP.

Responses were received from three respiratory specialists, the MO pharmacists and from a microbiologist who is a member of the Devon Antimicrobial Stewardship Group.

The FIG was asked to consider the proposed changes and approve the draft guidance for inclusion in the formulary pending clarification from the microbiologists of outstanding queries.

There was discussion about:

- The NICE recommendations on when treatment should be started. The Formulary team to determine whether these were intended to apply to treatment in a hospital setting.
- Duration of treatment – it was agreed to remove ‘review at 3 days’.
- will consider whether there may be any implication relating to this.
- Low Severity CAP – Treatment at home (oral antibiotics)
    - CBP score to be included
    - Duration of treatment - it was agreed to remove ‘review at 3 days’

It was agreed that the Formulary team will update the proposed formulary entry in line with the discussion. Once clarifications have been received from the microbiologist this will be brought back to FIG.

ACTION: Formulary team to update the proposed formulary guidance in line with the discussion and seek clarification from the microbiologist.

ACTION: Once clarification has been received from the microbiologist, Formulary team to bring the Pneumonia antimicrobial guidance back to FIG.

11. Cough (acute) guidance review: antimicrobial guidance (NICE)

Previously the Primary Care Antimicrobial Guidance was reviewed annually using the Public Health England (PHE) 'Management of Infection Guidance for Primary Care; NICE and PHE is now collaborating to provide guidance periodically.

The current formulary guidance has been reviewed in line with PHE and NICE Guideline NG120 Cough (acute): antimicrobial prescribing (February 2019). Notable changes are the inclusion of reference sources to appropriate NICE guidance, Self-care advice and NHS England's prescribing guidance for various common conditions for which over-the-counter (OTC) items should not be prescribed in primary care, antibiotic recommendations for children and young people under 18 years of age where they are indicated, referral guidelines links, reassessment criteria.

Doxycycline has become green (first line) antibiotic choice for adults aged 18 years and over, and Amoxicillin has become blue (second line). Clarithromycin and Erythromycin have been included as blue (second line) antibiotic treatment options.

The FIG considered and accepted the revised formulary guidance.

ACTION: Formulary Team to update the formulary with the accepted Cough (acute) guidance.

12. Chapter 14. Vaccines guidance review

The Formulary guidance for immunological products and vaccines has been considered as part of the rolling review programme. A proposed revision to the current vaccine chapter was presented. Alignment of the N&E and S&W guidance in the Devon Formulary was proposed to provide easily accessible information to primary care prescribers Devon-wide.

The proposed revised guidance was developed and updated using national and international guidelines. The guideline has undergone format changes and information has been consolidated to streamline the accessibility of clinically appropriate guidance and treatment options.

It was noted that the Formulary Team had e-mailed Bryan Foreshew regarding whether normal immunoglobulins for subcutaneous use need to be listed.

The FIG was asked to consider the proposed vaccine guidance and forward any comments to the Formulary team within two weeks. If no additional comments are received the guidance will be updated as presented.

ACTION: FIG members to consider the proposed vaccine guidance and forward any comments to the Formulary Team within two weeks.

ACTION: If no additional comments are received; Formulary team to update the guidance as presented.

13. Lidocaine Plasters

A patient leaflet has been produced by Torbay and South Devon NHS Foundation Trust to be given to patients starting Lidocaine plasters in acute trust settings also to patients started on Lidocaine plasters by GPs. The leaflet explains to patients that the plasters are only to be used for two weeks.

The FIG agreed that a link be included in the Devon formulary to the leaflet. The FIG also suggested that the leaflet be shared with other geographical areas.

Andrew Gunatillke to provide a link to the Torbay and South Devon patient leaflet for lidocaine plasters.

ACTION: Andrew Gunatilleke to provide a link to the Torbay and South Devon patient leaflet for lidocaine plasters.

ACTION: Formulary team to add link to the patient leaflet for lidocaine plasters to the Devon Formulary.

14. Recent drug decisions (including NICE)

The recent drug decisions were reviewed.

15. MHRA Drug Safety Updates: Oct and Nov 2019

<u>October 2019</u>

- Ingenol mebutate gel (Picato▼): increased incidence of skin tumours seen in some clinical studies. Add advice for healthcare professionals to guidance and product page.

ACTION: Formulary team to add advice for healthcare professionals to the formulary product page.

- Nivolumab (Opdivo); reports of cytomegalovirus (CMV) gastrointestinal infection or reactivation. Advice for healthcare professionals to be added to the product page.

ACTION: Formulary team to add advice for healthcare professionals to the formulary product page.

- Prescribing medicines in renal impairment: using the appropriate estimate of renal function to avoid the risk of adverse drug reactions. Advice for healthcare professionals to be added to the Urology chapter.

ACTION: Advice for healthcare professionals to be added to the Urology chapter.

- Adrenaline auto-injectors: recent action taken to support safety. There was discussion about the number of auto-injectors held by schools and supply shortages. The Formulary team will add MHRA advice to the product page.

ACTION: Formulary team to add MHRA advice to product pages.

November 2019

- Yellow fever vaccine: stronger precautions in people with weakened immunity and in those aged 60 years or older. Formulary team to add MHRA advice for Yellow fever to the formulary.

ACTION: Formulary team to add MHRA advice for Yellow fever vaccine to the formulary.

- Carfilzomib (Kyprolis): risk of reactivation of hepatitis B virus. Formulary team to add link to MHRA Drug Safety Update to the formulary.

ACTION: Formulary team to add link to MHRA advice for Carfilzomib (Kyprolis): risk or reactivation of hepatitis B virus to the formulary.

Letters and drug alerts sent to healthcare professionals in October 2019

- Ranitidine: pharmacy-level recalls: It was noted that there has been a number of pharmacy level recalls for ranitidine-containing products as a precautionary measure due to possible contamination with N-nitrosodimethylamine.

Summary of actions

	Action	Lead	Status
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.* *The Clinical Effectiveness team is working with providers on identifying patients who may be at risk of hydroxychloroquine retinopathy and where such patients should be referred for testing, who will do this and how it will be resourced.* *It was noted that the risk for patients of getting of hydroxychloroquine retinopathy is low. The Formulary Team is also looking at the prescribing guidance.* Draft SMS Guidance will be brought to a future FIG meeting.	Formulary team	Outstanding
19/28	*Formulary entry for Urinary Tract Infections to be updated in line with the discussion.* *The Formulary team is awaiting additional guidance from microbiologists.* *Comments have been received from Jim Greig. Steve Cooke is taking this forward.* Work is in progress.	Formulary team	On agenda
19/29	*Urinary tract infections - Slider for people over the age of 65 to be brought to a future meeting.* *Further queries had been received from Jim Greig. The Formulary Team will raise with Steve Cooke.* Work is in progress.	Formulary team	On agenda
19/83	*Accepted formulary entry for Dermisplus prevent pads to be added to the formulary.* This will be included in Chapter 17 - Wound Management.	Formulary team	Complete

19/89	*Add accepted formulary entry for UrgoClean Ag Dressing to the formulary.* This will be included in Chapter 17 – Wound Management.	Formulary team	Complete
19/94	Wound management review – ascertain whether a similar process for supply of dressings exists in Devon. Status of action to be followed up	Demelza Grimes Formulary team	Outstanding Outstanding
19/100	MHRA Drug Safety Updates – September: Elmiron (pentosan polysulfate sodium) advice to be added to the formulary when NICE TA 610 is added	Formulary team	Complete
19/102	Update formulary guidance for effective contraception and frequency of pregnancy testing when medicines with teratogenic potential are prescribed.	Formulary team	Outstanding
19/103	Loteprednol for the treatment of steroid responsive inflammatory eye conditions - on completion of CCG governance procedures add accepted formulary entry to the formulary.	Formulary team	Complete
19/104	Budesonide 2mg/dose rectal foam – update formulary with the accepted formulary entry subject to receipt of a DoI from the applicant.	Formulary team	Outstanding
19/105	UCS Debridement – add accepted formulary entry for 17.5.3 Physical debridement pads to the formulary.	Formulary team	Complete
19/106	Ondansetron for nausea and vomiting in pregnancy: new safety information – check whether other antiemetic drugs included in the formulary section on the treatment of nausea and vomiting in pregnancy and hyperemesis gravidarum are licensed for this indication.	Formulary team	Outstanding
19/107	Update formulary guidance for ondansetron with the approved wording.	Formulary team	Complete
19/108	Update formulary with the accepted formulary entry for One-Alpha as the preferred brand of alfacalcidol when all strengths of capsules are available at wholesalers.	Formulary team	Complete
19/109	Amend formulary guidance for COPD in line with the discussion.	Formulary team	Complete
19/110	Pneumonia guidance – proposed antimicrobial guidance to be updated in line with the discussion and clarification sought from microbiologists.	Formulary team	Complete
19/111	On receipt of clarification from microbiologists Pneumonia antimicrobial guidance to be brought back to FIG.	Formulary team	On agenda
19/112	Cough (acute) guidance review: antimicrobial guidance – formulary to be updated with the accepted guidance.	Formulary team	Complete

19/113	Proposed vaccine guidance to be considered and comments forwarded to the formulary team within two weeks.	FIG Members	Complete
19/114	If no additional comments are received from FIG members the vaccine guidance will be updated as presented.	Formulary Team	Complete
19/115	Forward the link to Torbay and South Devon patient leaflet for lidocaine plasters to the Formulary team.	Andrew Gunatilleke	Outstanding
19/116	Link to patient leaflet for lidocaine plasters to be added to the Devon Formulary.	Formulary team	Outstanding
19/117	Ingenol mebutate gel (Picato▼) Add advice for healthcare professionals to the formulary product page.	Formulary team	Complete
19/118	Nivolumab (Opdivo) Advice for healthcare professionals to be added to the product page.	Formulary team	Complete
19/119	Prescribing medicines in renal impairment - Advice for healthcare professionals to be added to the Urology chapter.	Formulary team	Outstanding
19/120	Adrenaline auto-injectors – MHRA advice to be added to the product pages.	Formulary team	Complete
19/121	MHRA advice for Yellow fever vaccine to be added to the formulary.	Formulary team	Complete
19/122	Carfilzomib (Kyprolis): risk of reactivation of hepatitis B virus. Link to MHRA Drug Safety Update to be added to the formulary.	Formulary team	Complete