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

Meeting of the South and West Devon Formulary Interface Group

Minutes

Wednesday 14th November 2018: 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 Foundation Trust
Josh Hamilton	GP	Kernow CCG
Matt Howard	Clinical Evidence Manager	NEW Devon CCG
Paul Humphriss	Advanced Clinical Pharmacist	Livewell Southwest
Tom Kallis	Community Pharmacist	
Phil Melluish	GP	South Devon and Torbay CCG
Bill Nolan	GP	South Devon and Torbay CCG
Iain Roberts	Lead MO Pharmacist	South Devon and Torbay CCG
Graham Simpole	Joint Formularies Support Pharmacist	NEW Devon CCG
Christopher Sullivan	Pharmacist	Devon Partnership NHS Trust
Darren Wright	Joint Formularies Technician	NEW Devon CCG

Guests:

Anthony Mitchell	Clinical Pharmacist Prescriber	Livewell Southwest / University Hospitals Plymouth NHS Trust
Holly Barker	Pre-registration Pharmacist	Royal Devon and Exeter NHS Foundation Trust
Emily Hoile	Physiotherapist	Torbay and South Devon NHS Foundation Trust
Sarah Marner	MO Pharmacist	NEW Devon CCG

In attendance:

Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NEW Devon CCG

1. Welcome and announcements

Apologies

Peter Rowe	Consultant Nephrologist, Assistant Medical Director	University Hospitals Plymouth NHS FT
Andy Craig	GP	NEW Devon CCG
Lily Hammarlund-Sim	Pharmaceutical Advisor	NHS Kernow
Tony Perkins	Senior Medicines Optimisation Pharmacist	NEW Devon CCG
Emma Gitsham	Joint Formularies Pharmacist	NEW Devon CCG
Trudy Bown	Chief Pharmacy Procurement & IT Manager	University Hospitals Plymouth NHS FT
Nicola Joyce	Pharmacist	Livewell Southwest

In the absence of Peter Rowe, Andrew Gunatilleke chaired the meeting.

Sarah Marner attended the meeting as MO pharmacist for NEW Devon CCG in the absence of Tony Perkins.

Paul Humphriss attended the meeting as Livewell Southwest Pharmacist representative in the absence of Nicola Joyce.

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
Fluticasone furoate, umeclidinium bromide and vilanterol (Trelegy® Ellipta®) for chronic obstructive pulmonary disease (COPD)	Glaxo SmithKline UK
Alternative treatments	
Any other monotherapy or combination inhalers for COPD	Various manufacturers
Insulin Degludec (Tresiba®) for type 1 diabetes	Novo Nordisk Ltd
Alternative treatments:	
Insulin detemir (Levemir®) Insulin glargine (Abasaglar®, Lantus®, Toujeo®)	Novo Nordisk Ltd Eli Lilly and Company Ltd, Sanofi
Kyleena® 19.5mg intrauterine system (IUS)	Bayer Plc
Alternative LNG-IUS: Jaydess® Levosert® Mirena®	 Bayer Plc Gedeon Ritcher (UK) Ltd Bayer Plc

Cetraxal® (ciprofloxacin 2mg/ml ear drops solution)	Aspire Pharma Ltd
Reclassification of ulipristal acetate 5mg tablets (Esmya®) from amber to red	Gedeon Richter (UK) Ltd
Ikervis® (Ciclosporin) eye drops (Red to Amber) Alternative treatments: Capimune® Neoral® Sandimmun®	Santen UK Limited Generics UK/ T/A Mylan Novartis Pharmaceuticals UK Ltd Novartis Pharmaceuticals UK Ltd
Management of Infantile colic Colief® Infacol®	 Crosscare Limited Teva UK Limited
Anal irrigation systems Various systems	 Various manufacturers
Anal inserts Renew Insert® Peristeen® Anal Plug	 Renew Medical UK Ltd Coloplast Ltd
Unipolar depression Various medications	 Various manufacturers

e-FIG item	**Company**
Acute otitis media in children and young people Various medications	 Various manufacturers
Lyme disease Various medications	 Various manufacturers
Sodium alginate and potassium bicarbonate for the treatment of symptoms of laryngopharyngeal reflux Acidex Advance® Peptac® oral solution Alternative medications	 Pinewood Laboratories Limited Teva UK Ltd Various manufacturers

Name	Declaration
Tom Kallis	Devon LPC receives sponsorship from various pharmaceutical companies for LPC training events/evenings. *At the meeting it was noted that Mr Kallis was in attendance as a community pharmacist, not formally representing LMC*

2. Minutes of the meeting held on 5th September 2018 and matters arising

The minutes of the meeting held on Wednesday 5th September 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.* This is an extensive piece of work that is underway.	Formulary Team	Outstanding
18/78	*DMARDs for rheumatology (update) Confirmation to be provided to FIG once this has been through GP processes and feedback on themes discussed*. This was reported under matters arising.		Complete
18/79	*First generation (typical) depot antipsychotics – comments on proposed guidance to be forwarded to the Formulary Team.* *No additional comments were received.* A meeting is taking place on 7th December 2018 between NEW Devon CCG and Devon Partnership NHS Trust.		Complete
18/80	Opicapone for Parkinson's Disease – on completion of governance processes opicapone for Parkinson's disease to be added to the formulary in line with the discussion.		Complete
18/81	Contact to be made with Trudy Bown and Paul Foster about the possible removal of Sinemet® from the formulary and update the formulary entry for co-careldopa as agreed. This has been done and removed.		Complete
18/82	Local specialists to be contacted and agreement sought for the removal of tolcapone from the formulary. This was not agreed. Tolcapone is retained as a 'red' drug.		Complete

18/83	6.3.1 Bramox® products to be added to note 4 of the replacement therapy guidance.		Complete
18/84	Formulary entry for Tinidazole for giardiasis to be added to the formulary in line with the discussion.		Complete
18/85	Formulary entry for the Management of Constipation in Children to be added in line with the discussion.		Complete
18/86	Acute otitis media in children and young people to be progressed via the e-FIG process.		Complete
18/87	Lyme disease – clarification to be sought of the rational for NICE recommending IV ceftriaxone in favour of oral treatments.		Complete
18/88	Proposed guidance for Lyme disease to be updated in line with the discussion and circulated for approval via the e-FIG process.		Complete
18/89	Asthma and supporting treatment guidance to be updated in line with the discussion.		Complete
18/90	MHRA drug safety update guidance for Dolutegravir (Tivicay▼, Triumeq▼, Juluca▼) to be added to the formulary.		Complete
18/92	Darunavir boosted with cobicistat (Red drug) – Headline and link to MHRA drug safety guidance to be added to the formulary.		Complete
18/93	MHRA drug safety updates for pressurised metered dose inhalers (pMDI) link to be added to the formulary and linked to all pMDI pages.		Complete
18/94	Eltrombopag (Revolade) add link to MHRA drug safety update.		Complete
18/95	Parenteral amphotericin B - add all points from the safety update to the formulary.		Complete
18/96	Esmya (ulipristal acetate) – issues to be discussed with specialists and brought back to FIG. Item included on agenda		Complete

Matters Arising

- DMARDs

  The shared care/SMS guidelines have been considered. It is believed that they have been accepted in South Devon.

  In West Devon wording changes and clarifications have been requested. The finalised West Devon SMS guideline for DMARDs in rheumatology will be circulated to the FIG.

ACTION: Formulary Team to circulate the finalised West Devon SMS guideline for DMARDs in rheumatology.

- Hydroxychloroquine

  There was discussion about Hydroxychloroquine shared care. A member of the Clinical Effectiveness Team is undertaking some work on hydroxychloroquine monitoring following publication of guidelines by the Royal College of Ophthalmologists (RCO).

- Report of e-FIG decisions

The FIG received a report of the three e-FIG decisions taken since the last FIG meeting. These were:

- Acidex advance®

Responses received generally indicated acceptance of the proposed reintroduction of sodium alginate and potassium bicarbonate (as Acidex Advance brand) to the formulary for reducing symptoms of laryngopharyngeal reflux.

The Formulary has been updated.

- Acute otitis media in children and young people

Responses received on the proposed guidance for acute otitis media in children and young people indicated acceptance of the proposals.

The update is due to be published.

ACTION: Formulary team to publish update for acute otitis media in children and young people.

- Lyme Disease

Responses received indicated acceptance of the proposal. The responses included comments about the guideline to use IV ceftriaxone for Lyme disease with central nervous system (CNS) involvement. It had been suggested that the IV preparation could be 'Red' (hospital only) in the formulary. However, the Formulary team suggested that further work be undertaken.

It was noted that the 'Red' colour status would be for Lyme disease with CNS only. The FIG indicated that the proposed wording may need to be tightened. The Formulary Team will consider the output of the Antimicrobial Stewardship Group and discuss with Phil Melluish and Paul Humphriss.

ACTION: Formulary Team to consider the output of the Antimicrobial Stewardship Group and discuss with Phil Melluish and Paul Humphriss.

3. Fluticasone furoate, umeclidinium bromide and vilanterol (Trelegy® Ellipta®) for chronic obstructive pulmonary disease (COPD)

At its meeting on 9th September 2018 the Clinical Policy Committee made a decision to recommend the routine commissioning of Trelegy Ellipta combination dry power inhaler in Devon for the treatment of adult patients with moderate to severe COPD. This recommendation has recently been accepted by the CCG's executive body.

The FIG considered the proposed formulary entry. There was discussion about cost and efficacy; Trelegy Ellipta is cheaper than most other triple therapy combinations options with 2 or more inhalers. Trelegy Ellipta is the same price as Trimbow.

The FIG accepted the proposed formulary entry for Trelegy Ellipta.

At the time of the decision Trelegy Ellipta was not licensed for switching of patients who are already stable on triple therapy or, patients not adequately controlled on therapy other than inhaled corticosteriod (ICS)/long acting β_2-agonists (LABA). The Formulary team have been informed that the licence has recently been extended, however the SPC has yet to be updated.

It was agreed that Note 1 'Trelegy is only licenced for use in moderate to severe COPD in patients who are not adequately treated by a combination of ICS/LABA' be removed when the summary of product characteristics (SPC) is updated.

ACTION: Formulary team to add the proposed entry for Trelegy Ellipta to the formulary in line with the discussion.

4. Insulin Degludec (Tresiba®) for type 1 diabetes

At its meeting on 9th September 2018 the Clinical Policy Committee (CPC) made a decision to recommend the routine commissioning of Insulin Degludec (Tresiba) for the treatment of Type 1 Diabetes. This recommendation has recently been accepted by the CCG's executive body. CPC did not recommend Insulin Degludec be routinely commissioned for the treatment of Type 2 Diabetes.

The FIG discussed the proposed formulary entry for Tresiba. It was noted that Tresiba provides good value for money. There was discussion about Note 3b of the proposed entry, 'Do not convert (ie, recalculate) doses when transferring patients from one strength of insulin degludec to another. The pen device shows the number of units of insulin to be injected irrespective of strength'. This will be amended for clarity.

It was agreed that information be added to the top of each entry for insulin degludec highlighting the different strengths. The FIG accepted the proposed formulary entry with minor amendment.

ACTION: Formulary Team to add the proposed formulary entry for Insulin Degludec (Tresiba®) to the formulary in line with the discussion.

5. Consideration of Kyleena® (levonorgestrel) 19.5mg IUS for addition to the formulary

An application has been received from an Associate Specialist in Community Contraception and Sexual Health at Livewell Southwest to consider the inclusion of Kyleena 19.5mg intrauterine system (IUS) as a green (first line) option for contraception in women.

The applicant has stated that there is low uptake of IUS as a method of contraception in younger women in the UK. The key concern is ease of insertion in women who have not given birth, and the potential discomfort of the insertion process. The applicant also suggested that as Kyleena has smaller dimensions compared to other IUS preparations it may be a more favourable option.

It is proposed that Kyleena is used as an option for contraception in women for whom a 5-year levonorgestrel intrauterine systems (LNG-IUS) is appropriate. The other current formulary 5-year LNG-IUS option is Mirena®, which is available at a higher acquisition cost, but can be used in other indications. Jaydess® and Levosert® are included in the formulary as 3-year and 4-year IUS options for contraception.

The FIG considered and accepted the proposed addition of Kyleena to the formulary. There was discussion about the number of 5-year products included in the formulary. There was also discussion about the license, cost effectiveness and failure rate of Kyleena; the failure rate appears to be slightly higher than for Mirena, the existing formulary product providing contraception for up to five years.

ACTION: Formulary Team to add agreed updated formulary entries to the formulary.

6. Consideration of Cetraxal® (ciprofloxacin) 2mg/ml ear drops for addition to the formulary

An application has been received for the consideration of Cetraxal (ciprofloxacin) 2mg/ml ear drops solution from Mr James Powles, Consultant ENT Surgeon (Torbay and South Devon NHS Foundation Trust) as a green (first line treatment) for the management of acute otitis externa. Cetraxal 2mg/ml ear drops solution in single dose containers is the first ciprofloxacin-only licensed topical treatment indicated for the treatment of acute otitis externa (AOE) in adults and children older than 1 year with an intact tympanic membrane, caused by ciprofloxacin susceptible microorganisms. Each preservative-free, single-dose ampoule delivers 0.25ml of solution that contains 0.5mg of ciprofloxacin. The contents of one single ampoule should be instilled into the affected ear twice a day for seven days.

There is limited formulary guidance for the treatment of acute otitis externa. Currently ciprofloxacin 0.3% eye drops is included as a blue (second line) option for the treatment of this indication (unlicensed). NICE Clinical Knowledge Summary 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, proposed that Cetraxal would replace the current formulary unlicensed product for the treatment of acute otitis externa and the colour of the entry would be revised from ‘blue’ to ‘green’. Ciprofloxacin 0.3% eye drops would remain as an ‘amber’ (specialist) anti-infective eye preparation for the treatment of bacterial eye infections and corneal ulceration.

The FIG was asked to consider the proposed addition to the formulary of Cetraxal (ciprofloxacin) 2mg/ml ear drops for the management of acute otitis externa and suppurative otitis media (unlicensed indication).

There was discussion about whether an antimicrobial was sufficient without a steroid. GPs present stated that they usually used a combined product including a steroid as the condition was often itchy. It was agreed that the Formulary Team would contact microbiologists regarding the queries raised.

ACTION: Formulary team to contact microbiologists to seek advice on whether a steroid is needed.

7. Reclassification ulipristal acetate 5mg (Esmya®) from amber to red

Ulipristal acetate (UPA) is an orally active selective progesterone receptor modulator (SPRM); it exerts a direct action on fibroids reducing their size through inhibition of cell proliferation and induction of apoptosis.

UPA 5mg tablets (Esmya) are included in the South and West Devon Formulary as an amber (specialist use) medicine for the pre-operative treatment of moderate to severe symptoms of uterine fibroids, and for the intermittent treatment of moderate to severe symptoms of uterine fibroids (up to four courses), in line with NICE CG44.

In March 2018, the Medicines and Healthcare products Regulatory Agency (MHRA) introduced temporary safety measures for Esmya following reports of serious liver injury. The European Medicines Agency (EMA) undertook an EU-wide review of the evidence and the formulary drug monographs were updated to reflect these measures. UPA 30mg for emergency contraception is not affected by these measures.

Following completion of the EMA safety review the licenced indications of Esmya have been updated to allow one course of pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age and intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age who are not eligible for surgery.

Following consultation with specialists at each of the acute hospital trusts in Devon it is proposed that ulipristal acetate 5mg tablets (Esmya) be reclassified from amber (specialist) to red (secondary care). This is also in line with the North and East Devon Formulary.

The FIG discussed the proposed formulary entry.

Subject to the addition of a note stating that ‘the prescriber is responsible for ensuring drug safety monitoring is undertaken’ being added to the formulary entry, the FIG accepted the proposed formulary entry reclassifying ulipristal acetate 5mg (Esmya) from ‘amber’ to ‘red’.

ACTION: Formulary Team to update the formulary entry reclassifying ulipristal acetate 5mg (Esmya) from ‘amber’ to ‘red’ in line with the discussion.

8. Reclassification of ciclosporin 1mg/ml single use eye drops (Ikervis®) from red to amber

Ciclosporin 1mg/ml single use eye drops (Ikerivs) were added to the formulary as a red (secondary care only) drug following publication of the positive NICE technology appraisal (TA) guidance: Ciclosporin for treating dry eye disease that has not improved despite treatment with artificial tears (TA369, December 2015). An application was received from Ophthalmologists from University Hospitals Plymouth NHS Trust to consider reclassification of ciclosporin to amber (specialist input) status to allow continuation of prescribing in primary care, following specialist initiation, with a review required by an ophthalmologist specialist at least every six months.

It was proposed that the current ciclosporin drug entry 8.2.2 Corticosteriods and other immunosuppresents is split into two separate entries. Oral and I/V ciclosporin preparations will remain in Chapter 8, (Malignant disease) while ciclosporin eye preparations are proposed to move to Chapter 11 (Eye).

The FIG considered the two proposed formulary entries.

The proposal for Chapter 8, (Malignant disease) was accepted without amendment.

The proposal for Chapter 11, (Eye) was accepted subject to minor amendment:

- Note 1 – 'Ikervis treatment must be initiated by an ophthalmologist' to be amended to state 'including first prescription'.
- Note 2 – 'Response to treatment with Ikervis should be reassessed at least every 6 months …' add 'by specialist'.
- Note 3 – Add indication from NICE TA369.

There was discussion about patients with dry eye generally being seen in primary care. It was noted that patient's outpatient follow-up appointments can be delayed. The Formulary team were asked to seek specialist advice on the appropriate duration of continued prescribing by GPs, if a six month review has not been done. This information can be added to the entry when clarified.

There was also discussion about the cost implications.

ACTION: Formulary Team to update the two formulary entries (Chapter 8, Malignant disease and Chapter 11 Eye) in line with the discussion.

9. Infantile colic

Formulary guidance for the management of infantile colic has been considered as part of the rolling review process. It is proposed to align the North and East, and South and West Devon Formularies to provide accessible information to primary care prescribers. The proposed entry was an amalgamation of the information currently included in both the South and West Devon Formulary and in the North and East Devon Formulary with some additional information from NICE and local specialists.

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

ACTION: Formulary Team to update the formulary guidance for Infantile Colic.

1.1.1 Antacids and simeticone

There was discussion about Infacol® and whether it is required in the formulary. Currently it is included as a secondary care only (Red) drug to be used specifically for pre-endoscopy/video capsule for improved clarity. It was agreed that the Formulary Team would contact Trudy Bown to ascertain if infacol is still required in the formulary. It was noted that it is not necessary for every medicine used in secondary care to be included in the formulary.

ACTION: Formulary Team to contact Trudy Bown to ascertain if infacol can be removed from the formulary.

10. Unipolar depression

The Devon Formularies are in the process of revising and updating the mental health guidelines. The first topic subject to review is unipolar depression. A revised draft has been written with reference to NICE Clinical Guidelines and Devon Partnership NHS Trust (DPT) prescribing guidelines. The current Devon formulary antidepressant entries are also subject to update. The Formulary Team noted that NICE guidance is due to be published in December 2019.

The proposals had been circulated to specialists for comment. Subsequent to circulation of the meeting papers additional comments were received from Amanda Gulbranson (Child and Adolescent Mental Health Service, CAMHS). The FIG was informed of these comments as part of the discussion.

The FIG considered the proposed formulary guidance for unipolar depression:

- Antidepressant treatment options
  - All Selective serotonin reuptake inhibitors (SSRIs) will have 'green' first line status in the formulary.
  - The order of the drugs in the formulary to be amended so that fluoxetine appears below sertraline and above escitalopram.
  - It was agreed that paroxetine is not needed in the formulary.
  - Alternative antidepressants – Trazodone to be reclassified as an 'amber' specialist product.
- Stopping and switching between antidepressants
  - Information to be added to give detail on Serotonin syndrome.
- Depression in pregnancy and the postnatal period.
  - Add note stating that women can self-refer to the depression and anxiety service.
- Depression in children and adolescents.
  - Keep information in 'red' box.
- Resources, clinical referral guidelines and references.
  - Add MHRA guidance on SSRIs and SNRIs use and safety (2014).
- 4.3.1 Tricyclic and related antidepressant drugs
  - Nortriptyline – this is for neuropathic pain and is not recommended for depression. Can continue for existing patients.
- 4.3.3 Selective serotonin re-uptake inhibitor
  - Keep information in red box.

- Fluoxetine – add 20mg dispersible tablets.
- 4.3.4 Other antidepressant drugs
  - Venlafaxine - Add MHRA (2014) guidance on SSRIs and SNRIs: Use and Safety

Formulary team to redraft in line with discussions, liaise with specialists and bring back to future FIG meeting.

ACTION: Formulary Team to redraft in line with discussion, liaise with specialists and bring back to future FIG meeting.

11. Anal irrigation systems

Anal irrigation systems introduce water into the bowel via a rectal catheter/cone; the water simulates the bowel, and flushes out the stool. Anal irrigation is usually performed daily or on alternate days. These systems may be used to control constipation and/or faecal incontinence resulting from neurogenic or non-neurogenic disorders.

Non-mandatory NICE medical technologies guidance (MTG) identifies a number of treatment options for bowel dysfunction. The MTGs indicate that changes to diet and physiotherapy and long-term management strategies such as transanal irrigation should be considered. A number of anal irrigation systems are available for prescription on the NHS, featuring manual or electric pumps. Currently the South and West Devon Formulary does not include reference to anal irrigation systems.

Emily Hoile, Specialist Pelvic Health Physiotherapist, Torbay and South Devon NHS FT attended the meeting for the discussion of anal irrigation systems and explained how they worked to the FIG.

The FIG considered the proposed formulary entry. There was discussion about the potential costs, the role of the Goldcare distribution company nurse and ensuring that patients are aware of a range of products. It was noted that Goldcare does not have any irrigation systems of its own there was also discussion about patients being made aware of other supply routes. Emily Hoile suggested that she draw up a document stating that patients assessed by the Goldcare nurse but must be made aware that they have a choice of the route of supply of products.

It was agreed that the Formulary Team would add 'ensure that patients are aware that they have a choice of the route of supply of products' to the formulary entry.

ACTION: Formulary Team to add the formulary entry for anal irrigation systems to the formulary in line with the discussion.

12. Anal inserts

Anal inserts (also known as anal plugs) are single use continence devices which act as a physical barrier to prevent leaks for patients with faecal incontinence. The inserts are usually made of foam or silicone; they do not deal with the underlying condition but may be useful as a coping strategy for some patients. NICE Clinical Guideline 49 (faecal incontinence in adults: management) states that 'People with faecal incontinence should be offered…anal plugs (for people who can tolerate them)…'. Two brands of anal plug are currently available on for prescription on NHS FP10 (Peristeen® and Renew®). Neither device is currently referred to in the South and West Devon Formulary.

Emily Hoile, Specialist Pelvic Health Physiotherapist, Torbay and South Devon NHS FT attended the meeting for the discussion of anal inserts.

Emily Hoile explained to the FIG how and why anal inserts were used. It was noted that there are only two products available and that they are prescribed by GPs following recommendation by specialist services.

The FIG accepted the proposed formulary entry for anal inserts without amendment.

ACTION: Formulary team to add the accepted formulary entry for anal inserts to the formulary.

13. Recent drug decisions (including NICE)

The recent drug entries were noted.

14. MHRA Drug Safety Updates: Sept '18 & Oct '18

<u>September 2018</u>

- Valproate Pregnancy Prevention Programme: actions required now from GPs, specialists, and dispensers. Nothing new has been included in this drug safety update. No action required.
- Xofigo▼ (radium-223-dichloride): new restrictions on use due to increased risk of fracture and trend for increased mortality seen in clinical trial. This is a 'Red' secondary care only drug. It was agreed that no action was required.
- Daclizumab beta (Zinbryta▼): risk of immune-mediated encephalitis – some cases several months after stopping treatment. Information to be included. An earlier warning had been included with a date set for removal after six months, this will now be amended to twelve months.
- Nusinersen (Spinraza▼): reports of communicating hydrocephalus; discuss symptoms with patients and carers and investigate urgently. This is not in the formulary. No action required.

<u>October 2018</u>

- Rivaroxaban (Xarelto▼) after transcatheter aortic valve replacement (TAVR): increase in all-cause mortality, thromboembolic and bleeding events in patients in a clinical trial. The following points will be added to the rivaroxaban entry.

    - rivaroxaban is not authorised for thromboprophylaxis in patients with prosthetic heart valves, including patients who have undergone TAVR, and should not be used in such patients
    - rivaroxaban treatment in patients who undergo TAVR should be stopped and switched to standard of care

ACTION: Formulary team to add agreed information to the formulary entry for rivaroxaban.

- Ritonavir-containing products: reports of interaction with levothyroxine leading to reduced thyroxine levels. Add a link to the MHRA safety update and the following:

    - monitor thyroid-stimulating hormone (TSH) in patients treated with levothyroxine for at least the first month after the start and end of ritonavir treatment

ACTION: Formulary team to amend formulary entry for ritonavir-containing products in line with the discussion.

- Ponatinib (Iclusig▼): reports of posterior reversible encephalopathy syndrome. This is currently a 'Red' secondary care only drug. It was agreed that no action was required.

- Transdermal fentanyl patches: life-threatening and fatal opioid toxicity from accidental exposure, particularly in children. The drug safety information is already included in the formulary.

- A link to the update will be added to the transdermal fentanyl formulary entry for reference.

ACTION: Formulary team to add link to the transdermal fentanyl formulary entry for reference.

15. Confirmation of meeting dates 2019

Meeting dates for 2019 had been included in the Board Pack. Details of the venues for the meetings taking place on 13th March 2019 and 10th July 2019 will be circulated shortly.

ACTION: Formulary team to confirm venue for FIG meetings scheduled for 13 March 2019 and 10 July 2019.

16. Any Other Business

Medical Cannabis

The FIG discussed a proposal to add the contents of a letter developed for patients to the formulary. It was agreed that a clear statement was helpful. An e-mail had also been received from Larrisa Sullivan. It was noted that Sativex® is not routinely commissioned in Devon. GPs are not able to legally prescribe medical cannabis products. The FIG agreed not to add the letter but instead the Formulary Team will draft formulary information based on the letter and circulate to specialists for comment. It was agreed that this should be Devon wide if possible.

ACTION: Formulary Team to add Medical Cannabis information to the work plan.

It was agreed that Andrew Gunatilleke would feed-back comments on the letters (including re Sativex) to local specialists and forward re-drafted letters to the formulary team.

ACTION: Andrew Gunatilleke to feed-back comments on the letters (including re Sativex to local specialists and forward re-drafted letters to the Formulary Team.

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.* This is an extensive piece of work that is underway.	Formulary Team	Outstanding
18/97	Finalised West Devon SMS guideline for DMARDs in rheumatology to be circulated.	Formulary Team	Complete
18/98	Acute otitis media in children and young people – update to be published.	Formulary Team	Complete
18/99	Lyme disease – consider the output of the Antimicrobial Stewardship Group and discuss with Phil Melluish and Paul Humphriss.	Formulary Team	Complete
18/100	Add proposed entry for Trelegy Ellipta to the formulary in line with the discussion.	Formulary Team	Complete
18/101	Add proposed entry for Insulin Degludec (Tresiba) to the formulary in line with the discussion.	Formulary Team	Complete
18/102	Add agreed updated formulary entry for Kyleena (levonorgestrel) 19.5mg IUS to the formulary.	Formulary Team	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.	Formulary Team	Outstanding
18/104	Formulary entry for ulipristal acetate 5mg (Esmya) to be reclassified from 'Amber' to 'Red' in line with the discussion.	Formulary Team	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 are proposed to move to Chapter 11.	Formulary Team	Complete
18/106	Accepted formulary guidance for Infantile Colic to be added to the formulary.	Formulary Team	Complete
18/107	Trudy Bown to be contacted to ascertain if Infacol can be removed from the formulary.	Formulary Team	Complete
18/108	Unipolar depression – formulary team to redraft guidelines in line with discussion, liaise with specialists and bring back to future FIG meeting.	Formulary Team	Complete
18/109	Formulary entry for anal irrigations systems to be added in line with the discussion.	Formulary Team	Complete
18/110	Accepted formulary entry for anal inserts to be added to the formulary.	Formulary Team	Complete
18/111	MHRA Drug Safety Update: October 2018 – Rivaroxaban (Xarelto▼) – add agreed information to the formulary.	Formulary Team	Complete

18/112	MHRA Drug Safety Update: October 2018 – Ritonavir containing products – add agreed information to the formulary.	Formulary Team	Complete
18/113	MHRA Drug Safety Update: October 2018 – Link to the update to be added to the transdermal fentanyl entry for reference.	Formulary Team	Complete
18/114	Venue for FIG meetings scheduled for 13 March 2019 and 10 July 2019 to be confirmed.	Formulary Team	Complete
18/115	Add Medical Cannabis information to the work plan.	Formulary Team	Outstanding
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	Andrew Gunatilleke	Outstanding