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 17th January 2018: 2:00 pm – 4.30 pm

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

Present:

Chris Roome (Chair)	Head of Clinical Effectiveness	NEW Devon CCG
Trudy Bown	Chief Pharmacy Procurement IT Manager	Plymouth Hospitals NHS Trust
Andy Craig	GP	NEW Devon CCG
Emma Gitsham	Joint Formularies Pharmacist	NEW Devon CCG
Lily Hammarlund Sim	Pharmaceutical Advisor	NHS Kernow
Matt Howard	Clinical Evidence Manager	NEW Devon CCG
Nicola Joyce	Pharmacist	Livewell Southwest
Paul Manson	Senior MO Pharmacist	NEW Devon CCG
Phil Melluish	GP	SD& T CCG
Bill Nolan	GP	SD&T CCG
Iain Roberts	Lead MO Pharmacist	SD&T CCG
Graham Simpole	Joint Formularies Support Pharmacist	NEW Devon CCG
Darren Wright	Joint Formularies Technician	NEW Devon CCG
Paul Humphriss	Advanced Clinical Pharmacist	Livewell Southwest

Guests:

Emma Kelly	Practice Pharmacist	SD&T CCG
Holly Smith	Pre-Reg Pharmacist	T&SD NHS FT
Tony Perkins	Pharmacist	Livewell Southwest

In attendance:

Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NEW Devon CCG

Apologies

Andrew Gunatilleke (Chair)	Consultant	T&S NHS FT
Mark Stone	Community Pharmacist	
Joshua Hamilton	GP	NHS Kernow

Declaration of Interests

Declarations of interest were collected and reported.

Name	**Declaration**
Holly Smith	*Any other interest (other than personal or family medical conditions) which could be seen as influencing views of the drug/device under condition.* Parents work for Astra Zeneca Pharmaceuticals in Macclesfield.
Trudy Bown	Travel, subsidiaries and accommodation to attend S teering group in London – Alliance Healthcare (14th -15th November 2017. Dinner – Mawdsley Brooks (2nd August 2017) Sponsor of change management training day – Novartis (10th November 17)
Tony Perkins	Current committee member NICE COPD guideline update group.
Iain Roberts	Received funding for joint training initiative - TEVA Welsh Centre for Pharmacy Professional Education (WCPPE) - Train the trainer: joint working initiative

2. Minutes of the meeting held on 8th November 2018 and matters arising

The minutes of the meeting held on Wednesday 8th November 2017 were approved.

Summary of actions

	Action	Lead	Status
17/35	Liothyronine - When available link to host website for specialist protocol for patients receiving liothyronine to be added to the formularies. Warwick Heale is organising a meeting.	Formulary Team	Pending specialists
17/52	Migraine guidance: amended migraine guidance to be brought back to a future meeting for agreement. This has been added to the formulary team work plan.		Complete
17/68 17/68a	*Management of low back pain and sciatica: Contact details/referral details for Mount Gould and Spring Back to be added to the formulary.* *It was subsequently noted that referral is via DRSS therefore there are no details to be added.* *08/11/17 – A brief discussion took place about opioid contracts and the potential for selective use of opioids as an option. Links to NEW Devon CCG opioid contracts to be forwarded to the formulary team.* It was noted that currently no CCG document exists. This could be developed in the future. A link could be added but this needs to be a prescriber decision. Information could be shared with Andrew Gunatilleke and South Devon and Torbay CCG.		Complete Complete
17/76	Soltel® to be added to the formulary as the preferred brand of Salmeterol for COPD and asthma in adults.		Complete
17/77	Soltel® to be added as the preferred brand of Salmeterol to the preferred brand page of the formulary.		Complete
17/78	Formulary Team to undertake further work with regard to Trimbow verses LABA/LAMA + ICS and its position in the formulary. This item is included on the agenda.		Complete
17/79	Buccal Midazolam: Guidance pages to be reviewed and relevant information added to the notes section of the formulary entry for Buccal Midazolam.		Complete
17/80	Midazolam oromucosal solution: Consideration to be given to reference to the licensed options for rectal administration of medication.		Complete

17/81	Current formulary entry for midazolam (Buccolam, Epistatus) to be removed and replaced with the proposed entry for Buccolam as the preferred brand of midazolam.		Complete
17/82	Formulary status of rivaroxaban to be amended from red to amber in line with the discussion.		Complete
17/83	Review of formulary choice oral nutritional supplements: contact details for dietitian to be e-mailed to Darren Wright for addition to the formulary entry.		Complete
17/84	Review of formulary choice oral nutritional supplements: Kernow information on ONS to be forwarded to Julie Kemmner		Complete
17/85	Medicines Optimisation colleagues to remind team of the occasional need for non-formulary prescribing of ONS.		Complete
17/86	Line to be added to the formulary stating that non-formulary prescribing of ONS may occasionally be recommended by a dietitian		Complete
17/87	Formulary entry for powder supplements to state that they should be reconstituted with fresh milk.		Complete
17/88	Formulary entry for complete ready to drink milkshake style sip feeds to be amended to state that patients discharged from hospital on Fresubin® can be prescribed Aymes®.		Complete
17/89	Formulary entry for high energy low volume sip feed to be amended in line with the discussion.		Complete
17/90	Formulary entry for dislike of sweet flavours to be amended in line with the discussion.		Complete
17/91	Formulary entry for constipation and low fibre intake to be amended to state that there must be input from a dietitian before patients begin these supplements.		Complete
17/92	Formulary entry for taste fatigue to be amended as per the agreed entry.		Complete
17/93	Formulary entry for pre-thickened drinks to be amended as per the agreed entry.		Complete
17/94	Formulary entry for semi solid desserts to be amended as per the agreed entry.		Complete
17/95	Reconstitution of ONS: Formulary to state ‘full fat milk’ where the formulary states that powder supplements are to be reconstituted with fresh milk.		Complete
17/96	*Opioid analgesics: difficulties experienced with Matrifen patches not sticking to be investigated and consideration given to adding a note to the formulary about allowing the sticky side of Matrifen patches to come into contact with the air to improve stickiness for some patients.* This will form part of the ongoing opioid review.		Complete

17/97	Opioid analgesics: Mezolar to be added to the formulary as an alternative to Matrifen	Formulary Team	Outstanding
17/98	Opioid analgesics: Clarification to be sought on points raised during discussion of morphine sulphate section.	Formulary Team	Complete
17/99	Opioid analgesics: Targinact® and Tapentadol® sections to be taken back to FIG following publication of NHS England guidance in November.	Formulary Team	Outstanding
17/100	Opioid analgesics: Opioid dependence section to be revised following discussion with substance misuse teams. This will form part of the ongoing opioid review.	Formulary Team	Complete
17/101	Morphine equivalent table to be added to the formulary entry for opioids. This will form part of the ongoing opioid review.	Formulary Team	Complete
17/102	On completion of all discussed and agreed amendments to the proposed formulary entry and following discussion with substance misuse teams where appropriate, proposed formulary entry to be brought back to the FIG for approval. This has been added to the work plan.	Formulary Team	Complete
17/103	MHRA Drug Safety Updates for October 2017 to be added to the formulary in line with the discussion.	Formulary Team	Complete

Matters arising: e-FIG 23 November 2017

Buccal midazolam

At the meeting on 8th November 2017 it was accepted that Buccolam would be the only formulary option of buccal midazolam. At the meeting it was suggested that an additional note covering unlicensed use versus licenced rectal diazepam be added. It was also agreed that the formulary team review the formulary prescribing guideline for buccal midazolam. A rational for the proposals and draft entries was circulated for comment and approval via the e-FIG process. Responses received indicated acceptance of the proposed formulary entry for buccal midazolam. The formulary has been updated.

Clozapine drug safety alert

Following discussion at the S&W FIG meeting on 8th November around the MHRA drug safety update highlighting potential gastrointestinal side effects of Clozapine, specialist advice was sought and it was suggested a formulary entry would, in this instance, be useful and prudent. A draft formulary entry was circulated for comment and approval via the e-FIG process. Responses received indicated acceptance of the proposed formulary entry for Clozapine. The formulary has been updated and a line added to advise treatment where constipation occurs with an osmotic and/or stimulant laxative.

3. Consideration of AirFluSal MDI for addition to the formularies (including removal of Seretide 125 and 250 Evohalers)

An application has been received from the MO team, NEW Devon CCG for AirFluSal (Salmeterol xinafoate and fluticasone propionate) 25microgram/125microgram and 25microgram/250microgram MDIs to be added into the formulary, for use in patients over 18 years with asthma, and for Seretide (Salmeterol xinafoate and fluticasone propionate) 25microgram/125microgram Evohaler, Seretide 25microgram/250microgram Evohaler, Sirdupla(Salmeterol xinafoate and fluticasone propionate) 25microgram/125microgram MDI and Sirdupla 25microgram/250microgram MDI to be removed from the formulary.

AirFluSal metered dose inhalers (MDI) are available at lower acquisition costs than the Seretide Evohaler and Sirdupla MDI equivalents.

The FIG considered the proposed formulary application. There was discussion about the cost savings and treatment of paediatric patients. Written comments received from Mark Stone noted the number of recent formulary changes and the difficulties this creates for clinicians in keeping up to date with the recommendations.

The proposed formulary application was approved subject to the following amendments:

- The two Sirdupla® Aerosol inhalation MDIs to be retained unless agreed otherwise with South Devon and Torbay CCG.
- Remove Seretide MDI 25microgram/125microgram and 25microcgram/250microcgram.
- Retain lowest dose Seretide product for paediatric use.

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

4. Consideration of AirFluSal Forspiro inhaler for addition to the formularies (including removal of Seretide 500 Accuhaler)

This application was withdrawn due to lack of support.

5. Consideration of Trimbow 87 micrograms/5 micrograms/9 micrograms pressurised inhalation for addition to the formularies

In November 2017 the S&W FIG considered the addition of Trimbow (beclomethasone dipropionate/formoterol fumarate dihydrate/glycopyrronium bromide to the joint formulary. However, at that time the group felt that further work was required with regard to Trimbow vs. LABA/LAMA + separate ICS and its position in the formulary

The FIG was subsequently asked to consider a further paper which addressed two questions:

- What is the rational for prescribing LABA + LAMA +ICS triple therapy in COPD as LABA/ICS + separate LAMA rather than LABA/LAMA + separate ICS?
- Given the restricted licence for Trimbow (maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteriod and a long-acting beta2-agonist), how does it fit into local guidance for the management of COPD?

Specialists had been contacted about the licence but no response had been received.

The FIG considered the presented paper. There was discussion about:

- The place in therapy of Trimbow. Trimbow is proposed for a small number of appropriate patients but in reality more patients are likely to be treated.
- Trimbow is cheaper than current alternatives. Other products will be become available.
- There are licencing issues.
- Triple therapy is included in NICE GOLD and local COPD guidelines.
- The lack of engagement from specialists; it was agreed that the S&W FIG decision be deferred until after the item is discussed at the N&E FIG meeting with a specialist present.

ACTION: Formulary Team to e-mail specialists regarding attendance at the N&E FIG meeting.

ACTION: Trimbow to come back to the S&W FIG following discussion at the N&E FIG

6. Neomag (magnesium glycerophosphate) 4mmol chewable tablets

An application has been received from the MO teams in NEW Devon CCG that Neomag® to be included in the formulary, as it offers a licenced magnesium glycerophosphate tablet preparation for the treatment of chronic magnesium loss or hypomagnesaemia. It is proposed that it be included as 'amber' in the formulary as an alternative treatment to Magnaspartate® Granules, for those patients who cannot tolerate high sugar content, or prefer a tablet formulation as opposed to drinking a solution.

Neomag is slightly more expensive than Magnaspartate® granules therefore is it proposed as a second line treatment, with Magnaspartate® Granules as the first line treatment.

It was also proposed that Magnesium Hydroxide be removed from formulary entry for the treatment of magnesium deficiency as it is unlicensed for this indication. However Magnesium Hydroxide will remain in the laxative section of the formulary.

The FIG accepted the proposed formulary entry without amendment.

ACTION: Formulary Team to add Neomag® to the formulary entry for magnesium products in line with the discussion.

7. Reclassification of Ciprofloxacin eye drops 0.3% from red to blue

Ciprofloxacin eye drops 0.3% are indicated for the treatment of corneal ulcers and superficial infections of the eye and adnexa caused by susceptible strains of bacteria. The drops are also use as an unlicensed product as an alternative to ototoxic ear drops for the treatment of otitis media with perforation of the tympanic membrane.

The FIG considered the proposed formulary entry. There was discussion about Ciprofloxacin eye drops 0.3% being used as a treatment for otitis media with perforation of the tympanic membrane. Specialists had indicated that the drops are suitable for this indication. The FIG suggested that the a note be added to the formulary entry stating that

licensed ciprofloxacin eye drops should be prescribed in preference to specials formulations of ear drops due to significant difference in cost.

ACTION: Formulary Team to amend the formulary status of Ciprofloxacin eye drops 0.3% from red to blue.

ACTION: Formulary Team to add a note to the formulary entry stating that licensed ciprofloaxin eye drops should be prescribed in preference to unlicensed specials formulation of ear drops.

8. Reclassification of sodium oxybate

Sodium oxybate is a central nervous system depressant, licensed for the treatment of narcolepsy with cataplexy in adult patients.

In July 2017, sodium oxybate oral solution 500mg/1ml was added to the formulary for the management of narcolepsy with cataplexy in adults aged 19 years and older, in line with specific criteria, following a commissioning decision from the Clinical Policy Committee. Sodium oxybate oral solution is currently listed as a red (secondary care only) treatment.

The commissioning policy for sodium oxybate requires specialist assessment of efficacy after 3 months of treatment. There is only one consultant neurologist who treats all patients across Devon, the sharing of care between specialist services and primary care is therefore suggested in order to reduce unnecessary outpatient appointments. A Specialist Medicines Service (SMS) prescribing guideline has recently been agreed between specialist services, NEW Devon CCG, and the Local Medical Committee (LMC). GPs will be recompensed for the additional work via the NEW Devon CCG SMS.

It is proposed that sodium oxybate be reclassified as ‘amber’ when used in line with the SMS prescribing guideline.

A discussion took place and the FIG agreed the proposed change in the formulary status of sodium oxybate from ‘red’ to ‘amber’ subject to acceptance of one of the two proposals presented in the paper.

ACTION: Formulary Team to amend the formulary status of sodium oxybate from ‘red’ to ‘amber’.

Further discussion took place around the funding position of South Devon and Torbay CCG and the FIG accepted one of the two proposals presented. The accepted proposal states that ‘for South Devon patients treatment with sodium oxybate remains in secondary care only’. For NEW Devon CCG patient’s sodium oxybate can be used in primary care in line with the SMS prescribing guideline.

ACTION: Formulary Team to amend the formulary entry for sodium oxybate as per the discussion.

9. Revised modafinil formulary entry

Modafinil is included in the South and West Devon formulary as an 'amber' (specialist input) option to manage excessive sleepiness associated with narcolepsy with or without cataplexy.

A prescribing guideline has recently been agreed between specialist services, NEW Devon CCG and the Local Medical Committee to support the safe prescribing and monitoring of modafinil in primary care for appropriate patients, when the GP is confident to undertake specific roles. GPs will be recompensed for the additional work via the NEW Devon CCG SMS.

The FIG considered the proposed formulary entry. There was discussion about patients with existing hypertension and heart disease as they need appointments at two week intervals, the group suggested that such patients may need to be seen by a specialist. The possibility that not all GPs will be willing to treat patients with narcolepsy with or without cataplexy was raised. These points are covered in the prescribing guideline.

There was also discussion about the treatment of patients in the North and East who do not have narcolepsy with or without cataplexy and that a pan-Devon approach is needed. The FIG accepted the proposed formulary entry without amendment.

ACTION: Formulary team to update formulary in line with the proposed formulary entry for modafinil.

10. Reclassification of eluxadoline from red to amber

Eluxadoline is indicated for use in diarrhoea-predominant irritable bowel syndrome (IBS-D).

NICE technology appraisal guidance TA471 "Eluxadoline for treating irritable bowel syndrome with diarrhoea" (August 2017) states that Eluxadoline is recommended as an option within its marketing authorisation for treating irritable bowel syndrome with diarrhoea in adults, only if:

- the condition has not responded to other pharmacological treatments (for example, antimotility agents, antispasmodics, tricyclic antidepressants) or
- other pharmacological treatments are contraindicated or not tolerated, and
- treatment is started in secondary care.

In line with statutory responsibilities eluxadoline has been added to the formulary. The current status of eluxadoline is 'red' hospital only. It has recently been highlighted by the NICDE Planning Advisory Group (NPAG) that prescribing of eluxadoline could continue in primary care after being commenced in secondary care and it is proposed that eluxadoline 75mg and 100mg tables be reclassified as amber (specialist use) to indicate that ongoing prescribing by GPs is considered appropriate.

The group considered the proposed reclassification of eluxadoline from 'red' to 'amber'. A number of issues were considered:

- IBS-D is a common condition.
- Eluxadoline is likely to be used for a small number of patients

- Treatment is initiated in secondary care. A review is carried out by specialists after four weeks. It is proposed that following the review treatment the care of patients continue in primary care.
- NICE have costed treatment on the basis that patients receive treatment for 26 weeks out of 52 on a start stop basis. The group felt this to be inaccurate.
- Specialists do not appear to have a particular interest in using eluxadoline.
- Although no responses were received in the South and West it was noted that one comment was received in the North and East regarding the safety of eluxadoline and risks of pancreatitis. This is also the subject of an MRHA safety update

The group did not accept the proposed reclassification of eluxadoline.

It was agreed that based on lack of specialist interest the current formulary entry would remain red.

11. Items which should not routinely be prescribed in primary care

In November 2017 NHS England (NHSE) and NHS Clinical Commissioners (NHSCC) published guidance for CCGs on 18 treatments that these organisations recommend should not be routinely prescribed in primary care. CCGs are "expected to have 'due regard' to the guidance in formulating local policies and making decisions about implementation".

The guidance also states that "in relation to some of the medicines consulted on, the consultation feedback included requests that the particular medicine should be formally placed on the 'blacklist'. NHSCC and NHS England will recommend that the Secretary of State for Health formally consider blacklisting of Co-proxamol, Glucosamine and Chondroitin, Herbal Treatments, Homeopathy, Lutein and Antioxidants, Omega-3 Fatty Acid Compounds, Rubefacients (excluding topical NSAIDs)" as they have been determined to be clinically inappropriate for use in the NHS. It is not known if or when any of these items may be added to the 'blacklist.

NHSE/NHSCC recommendations for each of these products advise CCGs that prescribers in primary care should not initiate the product for any new patient and that CCGs should support prescribers in deprescribing of the product/s and where appropriate, ensure the availability of relevant services to facilitate this change.

The FIG was asked to consider adopting recommendations for treatments considered by NHSE and NHSCC and any additional support that may be required to aid deprescribing these items:

<u>Co-Proxamol</u> - Co-proxamol was withdrawn from the UK market in 2007 due to safety concerns and is not currently in the S&W formulary. However it is still being prescribed to some patients across South and West Devon. It was proposed that an entry be added to the formulary stating that co-proxamol is not recommended for use due to significant safety concerns. Prescribers should not initiate co-proxamol for any new patient.

The FIG considered the proposed formulary entry. There was discussion about the known safety issues of this drug. It was agreed that 'in primary care' be removed from the proposed entry.

The FIG agreed the proposed formulary entry with minor amendment.

ACTION: Formulary team to add the agreed formulary entry for co-proxamol.

Dosulepin - Dosulepin is not currently included in the S&W Devon formulary, which contains a statement stating that dosulepin has been excluded from the formulary and that NICE do not recommended it due to toxicity. Dosulepin is not recommended as a hypnotic. However, it is estimated that approximately 1,000 to 2,000 patients are treated across South and West Devon.

It was proposed that an entry be added to the formulary stating that dosulepin is not recommended for use in primary care due to significant safety concerns. Prescribers should not initiate dosulepin for any new patient. If, in exceptional circumstances, there is a clinical need for dosulepin to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional.

The FIG considered the proposed formulary entry, it was agreed that both references to 'in primary care' be removed from the proposed entry. The FIG agreed the proposed formulary entry with this minor amendment.

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

Prolonged-release doxazosin (also known as doxazosin modified release) - NHSE/NHSCC state that prolonged release doxazosin is approximately six times the cost of doxazosin immediate release, and no benefits of prolonged release above immediate release were identified. Prolonged-release doxazosin is not currently included in the S&W formulary. However ePACT data suggests that approximately 425 patients were treated with 4mg and 8mg MR tablets across South and West Devon in the last year.

It is proposed that the current formulary for doxazosin be amended. The FIG considered the proposed formulary entry for doxazosin, it was agreed that 'in primary care' be removed from the proposed entry. The FIG agreed the proposed formulary entry with this minor amendment.

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

Immediate release fentanyl - Further work is to be undertaken locally in relation to this recommendation.

Glucosamine and chondroitin - Glucosamine and chondroitin are not currently included in the S&W Devon formulary, which contains a statement about lack of evidence of efficacy of glucosamine for osteoarthritis, and a NICE "do not do" notification (NICE CG177). However glucosamine and chondroitin are being prescribed in the South and West although it is not clear how many patients this involves.

The FIG discussed the current formulary entry and it was agreed that the word 'should' be changed to 'may' and that price information be removed from the sentence "Patients who wish to take glucosamine should purchase it over-the-counter; although prices vary it can be obtained for less than £5 a month".

In addition the FIG accepted the proposed addition of a note to the formulary, stating that due to lack of evidence for glucosamine and chondroitin prescribers should not initiate glucosamine and/or chondroitin for any new patient.

ACTION: Formulary team to update the formulary entry for glucosamine and chondroitin in line with the discussion.

Herbal treatments - Under a Traditional Herbal Registration there is no requirement to prove scientifically that a product works, the registration is based on longstanding use of the product as a traditional medicine.

Herbal products are not recommended in the S&W Devon formulary. The current formulary guidance on herbal treatments for menopause highlights the unregulated nature of compound bioidentical hormones and that the efficacy and safety of such products is unknown as is the quality and purity of such products.

The proposed formulary entry states that following national guidance from NHSE herbal treatments are not recommended for use in any condition due to lack of scientific evidence required to register these products.

The FIG discussed the current and proposed formulary entries.

The FIG agreed that information from NICE be deleted from the current entry for menopause.

ACTION: Information from NICE to be deleted from the formulary entry.

The FIG accepted the proposed formulary entry for herbal treatment without amendment.

ACTION: Formulary team to add the formulary entry for herbal treatment in line with the discussion.

Homeopathic treatments - Homeopathic products are not currently included in the S&W Devon Formulary.

The proposed formulary entry states that following national guidance from NHSE homeopathy is not recommended for use for any condition due to lack of clear or robust evidence of efficacy.

The FIG discussed and accepted the proposed formulary entry for homeopathic treatment without amendment.

ACTION: Formulary team to add the accepted formulary entry for homeopathic treatments.

It was further agreed that a separate section be created for herbal treatments and homeopathy on the formulary information page.

ACTION: Formulary team to create a separate formulary page section for herbal treatments and homeopathy on the formulary information page.

Lidocaine plasters - Further work is to be undertaken locally in relation to this recommendation.

Liothyronine (including Armour Thyroid and liothyronine combination products) - Work is being undertaken separately across the Devon by the Sustainability and Transformation Plan (STP) footprint. No further work is being undertaken by the formulary team.

Lutein and antioxidants - Further work is to be undertaken locally in relation to this recommendation.

Omega-3 Fatty acid compounds - Further work is to be undertaken locally in relation to this recommendation.

Oxycodone and naloxone combination product - Further work is to be undertaken locally in relation to this recommendation.

Paracetamol and tramadol combination product - NHSE/NHSCC guidance indicates that paracetamol/tramadol combination products are significantly more expensive than the individual components and that are no significant advantages in terms of efficacy or safety identified over individual products.

Paracetamol and tramadol combination products are not currently included in the S&W Devon formulary. However 12 months (Nov '16 to Oct '17) ePACT data show the approximately 32 patients across south and west Devon were prescribed the combination product.

It is proposed that an entry be added to the formulary stating that paracetamol and tramadol combination are not recommended for use due to significant extra costs and no evidence of efficacy or safety over the individual products. Prescribers should not initiate paracetamol and tramadol combination products for any new patient.

The FIG considered the proposed formulary entry, it was agreed that 'in primary care' be removed from the proposed entry. The FIG agreed the proposed formulary entry with this minor amendment.

ACTION: Formulary team to add the agreed formulary entry for paracetamol and tramadol combination products.

Perindopril arginine - The NHSE/NHSCC guidance notes that "the perindopril arginine salt version was developed as it is more stable in extremes of climate than the perindopril erbumine salt, which results in a longer shelf life. Perindopril arginine is significantly more expensive than perindopril erbumine". No clinical advantage of the arginine salt was identified.

Perindopril arginine is not currently included in the S&W Devon formulary; the formulary entry for perindopril erbumine contains a note that 'Perindopril should be prescribed generically as listed. Coversyl® Arginine is not dose equivalent and is not included in the formulary'. 12 months (Nov '16 to Oct '17) ePACT data show that approximately 40 patients were prescribed perindopril arginine across south and west Devon.

It is proposed that an entry be added to the formulary stating that perindopril arginine is not recommended for use due to significant extra costs and no evidence of efficacy or safety over the individual products. Prescribers should not initiate perindopril arginine for any new patient.

The FIG considered the proposed formulary entry. It was agreed that 'in primary' care be removed from the proposed entry'.

The FIG agreed the proposed formulary entry with this minor amendment.

ACTION: Formulary team to add the agreed formulary entry for perindopril arginine.

Rubefacients (excluding topical NSAIDs) - The NHSE/NHSCC guideline is clear that the recommendations for rubefacients apply to topical products containing nicotinate compounds, salicylate compounds, essential oils and camphor, but do not apply to topical NSAIDs. There is limited evidence of efficacy regarding rubefacients for treating osteoarthritis and NICE has issued a "do not do" statement.

It is estimated that across South Devon and Torbay and the Western Locality the cost of prescribing rubefacients between November 2016 and October 2017 was £74,032.11. It is not possible to estimate the number of patients treated.

Currently the South and West Formulary contains an entry for rubefacients. Subsequent to the publication of the new guideline from NHSE and NHSCC a new entry is proposed bringing the formulary in line with the new guideline.

The FIG accepted the proposed formulary entry.

ACTION: Formulary team to replace the current formulary entry for Rubefacients with the updated entry.

It was also agreed that the e-PACT data be forward to Iain Roberts and Paul Manson.

ACTION: Matt Howard to forward ePACT data to Iain Roberts and Paul Manson.

Once daily tadalafil -Further work to be undertaken locally in relation to this recommendation.

Travel vaccines - The NHSE/NHSCC guidance restates existing regulations with respect to vaccinations which should not be prescribed on the NHS exclusively for the purposes of travel. These vaccines should continue to be recommended for travel but the individual traveller will need to bear the cost of the vaccination. This is in line with current formulary information, with the exception of BCG, which is not currently included.

It is proposed that BCG be added to the current formulary list of "travel immunisations that cannot be given as an NHS service" as well as the statement from NHSE/NHSCC that "for all other indications, as outlined in Immunisation Against Infectious Disease – the green book – the vaccine remains free on the NHS."

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

ACTION: Formulary team to add the accepted formulary entry for travel vaccines.

Trimipramine - Trimipramine is not currently included in the South and West Devon formulary; however 12 months (Nov ’16 to Oct ’17) ePACT data suggest depending of the number of tablets per day each patient is prescribed a maximum of 618 patients are prescribed trimipramine.

It is proposed that an entry be added to the formulary stating that trimipramine is not recommended for use due to significantly higher costs; more cost-effective tricyclic antidepressants are available. Prescribers should not initiate trimiparmine for any new patient.

The FIG considered the proposed formulary entry, it was agreed that ‘in primary care’ be removed from the proposed entry. The FIG accepted the proposed formulary entry with this minor amendment.

ACTION: Formulary team to add formulary entry for trimipramine in line with the discussion.

Further discussion took place about the guidance and the guidance and other items.

12. Nausea and vomiting in pregnancy and hyperemesis gravidarum

During development of draft referral guidance by Devon Referral Support Services (DRSS) it was suggested that the formulary include additional guidance for the management of nausea and vomiting in pregnancy and hyperemesis gravidarum. It is intended that this guidance support primary care clinicians, and complement the referral guidance.

The FIG considered the proposed formulary guidance for the management of nausea and vomiting in pregnancy and hyperemesis gravidarum. There was discussion about the proposed formulary status and position of ondansetron within the treatment pathway, its safety, the dose required and the cost. It was agreed that the formulary team would undertake further work with regard to the issues raised and once complete bring Nausea and vomiting in pregnancy and hyperemesis gravidarum to a future meeting.

ACTION: Nausea and vomiting in pregnancy and hyperemesis gravidarum to be brought back to FIG on completion of further work around the status and position within the treatment pathway, safety, the dose of ondansetron required and the cost.

13. Migraine guidance

A proposed update to the South and West Formulary guidance for migraine was discussed at the July 2017 meeting of the South and West FIG. The update was based on the NICE clinical guideline 150 “Headaches in over 12s: diagnosis and management” and guidance developed by Dr Weatherby, migraine specialist at Derriford Hospital. Comments from Dr Medcalf (Torbay Hospital) were also discussed.

At the meeting in July the need for further amendments and updates was agreed. The new revised formulary guidance incorporates amendments relating to the risk of medication overuse headache and an update of outstanding actions:

- the potential for medication overuse headache has been made prominent in the section on migraine prophylaxis,
- the daily dose of amitriptyline has been clarified,
- a statement on botulinum toxin has been added to the section on prophylaxis of migraine with a cross reference to the product entry for botulinum toxin

Further areas identified at the FIG meeting in July 2017 were noted. The addition of candesartan to the formulary has been deferred. Migraine guidance for children and use of zolmitriptan nasal spray are awaiting the outcome of review and consultation in North and East Devon.

The FIG considered and accepted the presented amendments to the migraine guidance. Minor changes to the layout of the medication overuse section were suggested.

The migraine guidance will be published and further amendments brought to FIG for consideration when appropriate.

ACTION: Formulary Team to update the agreed sections of the formulary migraine guidance in line with the discussion.

14. Management of Hypertension

The formulary entry for the Management of Hypertension has been reviewed following the publication of NICE clinical guideline (CG127) update of November 2017. The current formulary guidance appears to be up to date with no major changes required as a result of the NICE guidance update.

Some minor issues have been identified and amendments are proposed with the input of local specialists. The FIG discussed the minor issues identified:

- Note added regarding ACE inhibitors and Angiotensin II receptor antagonists – avoid in pregnancy and women who are planning pregnancy unless absolutely necessary.
- It was agreed that the term ‘essential hypertension’ be changed to ‘primary hypertension’ throughout the document.
- It was agreed that as all GP computer systems have an embedded CV risk calculator no link is required in the formulary guidance.
- It was noted that NICE prefer the QRISK2 calculator. QRISK 3 is due to become available shortly. This may not be the same as the calculator embedded in GP computer systems.

The FIG accepted the proposed updated formulary guidance.

ACTION: Formulary Team to update the formulary guidance for the management of hypertension

15. Recent drug decisions (including NICE)

The FIG received the recent drug decisions and guidance published since the last meeting.

The Formulary Team to add review of NICE NG80 Asthma: diagnosis, monitoring and chronic asthma management to the work plan.

ACTION: The Formulary Team to add review of NICE NG80 Asthma: diagnosis, monitoring and chronic asthma management to the work plan.

16. MHRA Drug Safety Updates: November, December 2017 & January 2018

The MRHA Drug Safety Updates were discussed.

November 2017: Gentamicin: potential for histamine-related adverse drug reactions with some batches – no action required.

Quinine: reminder of dose-dependent QT-prolonging effects; updated interactions - Add

- *be aware of dose-dependent effects on the QT interval and use caution if prescribing quinine in patients:*
  - *with conditions that predispose to QT prolongation such as pre-existing cardiac disease or electrolyte disturbance*
  - *taking other medication that could prolong QT interval*
  - *with atrioventricular block*.
- monitor patients closely if administration of quinine with phenobarbital or carbamazepine is necessary; serum levels of these anticonvulsant medicines could become raised and cause anticonvulsant toxicity.
- consult the Summary of Product Characteristics for a full list of interactive medicines and potential adverse reactions.

Oral tacrolimus products: reminder to prescribe and dispense by brand name only – no action required.
Support our second social media campaign for suspected adverse drug reactions – no action required.

Antiepileptic drugs: updated advice on switching between different manufactures' products – it was noted that a large amount of advice is already included. Add:

- *patient-related factors should be considered when deciding whether it is necessary to maintain continuity of supply for a specific product*.

Table summarising the different categories of antiepileptic drugs, and advice for prescribing. *Category 3 – Add Brivaraceta.*

Updates to Public Health England Green Book on live-attenuated vaccine – no action required.

December 2017: Gadolinium-containing contrast agents: removal of Omniscan and iv Magnevist, restrictions to the use of other linear agents – no action required.

Cladribine (Litak, Leustat) for leukaemia: reports of progressive multifocal encephalopathy (PML); stop treatment if PML is suspected – no action required.

Radium-223 dichloride (Xofigo▼): do not use in combination with abiraterone and prednisone/prednisolone following clinical trial signal of increased risk of death and fractures - no action required.

Eluxadoline (Truberzi ▼): risk of pancreatitis; do not use in patients who have undergone cholecystectomy or in those with biliary disorders – no action required. This is a 'red'drug.

Fingolimod (Gilenya▼): new contraindications in relation to cardiac risk – no action required. This is a 'red drug'.

Fingolimod (Gilenya▼): updated advice about risk of cancers and serious infections – no action required. This is a 'red' drug.

January 2018: Daclizumab (Zinbryta▼) and risk of severe liver injury: new restrictions to use and strengthened liver monitoring – no action required.

Recombinant human erythropoietins: very rare risk of severe cutaneous adverse reactions (SCARs) – Add as darbepoetin alfa is amber with shared care guideline in Western locality:

- we are aware of very rare cases of severe cutaneous adverse reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TENS), in patients receiving recombinant human erythropoietins (r-HuEPOs); some cases were fatal
- more severe cases were recorded with long-acting r-HuEPOs (darbepoetin alfa and methoxy polyethylene glycol-epoetin beta)
- advise patients of the signs and symptoms of severe skin reactions at imitation and instruct them to stop treatment and seek immediate medical attention if they develop widespread rash and blistering; these rashes often occur following fever of flu-like symptoms.
- Discontinue all r-HuEPOs permanently in patients who develop severe cutaneous adverse reactions such as SJS or TEN.

ACTION: **Formulary team to identify commissioner of recombinant human erythropoietins**

Drug-name confusion: reminder to be vigilant for potential errors: no action required.

Co-dydramol: prescribe and dispense by strength to minimise risk of medication error – no action required. This will be considered as part of other work.

Herbal medicines: report suspected adverse reactions via the Yellow Card Scheme – no action required.

Summary of actions

	Action	Lead	Status
17/35	Liothyronine - When available link to host website for specialist protocol for patients receiving liothyronine to be added to the formularies. Warwick Heale is organising a meeting.	Formulary Team	Pending specialists
17/97	Opioid analgesics: Mezolar to be added to the formulary as an alternative to Matrifen	Formulary Team	Complete
17/99	Opioid analgesics: Targinact® and Tapentadol® sections to be taken back to FIG following publication of NHS England guidance in November.	Formulary Team	Outstanding
18/01	Formulary entry for AirFluSal MDI (including removal of Seretide 125/25 micrograms and 250/25 microgram Evohalers) to be amended in line with the discussion.	Formulary team	Complete
18/02	Trimbow 87 micrograms/5 micrograms/9 micrograms pressurised inhalation – specialists to be invited to attend the N&E FIG meeting	Formulary team	Complete
18/03	Trimbow to be brought to S&W FIG following discussion at the N&E FIG meeting.	Formulary team	Outstanding
18/04	Neomag 4mmol chewable tables to be added to the formulary entry for magnesium products in line with the discussion.	Formulary team	Complete
18/05	Formulary status of Ciprofloxacin eye drops 0.3% to be amended from red to blue.	Formulary team	Complete
18/06	Note to be added to the formulary entry for Ciprofloxacin eye drops 0.3% stating that these eye drops should be prescribed in preference to unlicensed specials formulation of ear drops.	Formulary team	Complete
18/07	Formulary status of sodium oxybate to be amended from ‘red’ to ‘amber’.	Formulary team	Complete
18/08	Formulary entry for sodium oxybate to be amended in line with the discussion.	Formulary team	Complete
18/09	Formulary to be updated in line with the proposed formulary entry for modafinil.	Formulary team	Complete
18/10	Co-Proxamol - agreed entry to be added to the formulary.	Formulary team	Complete
18/11	Dosulepin – agreed entry to be added to the formulary.	Formulary team	Complete
18/12	Doxazosin – agreed entry to be added to the formulary.	Formulary team	Complete

18/13	Formulary entry for glucosamine and chondroitin to be updated in line with the discussion.	Formulary team	Complete
18/14	Formulary entry for herbal treatments to be updated in line with the discussion.	Formulary team	Complete
18/15	Formulary entry for homeopathic treatments to be added to the formulary.	Formulary team	Complete
18/16	Separate formulary section for herbal treatment and homeopathy on the formulary information page.	Formulary team	Complete
18/17	Agreed formulary entry for paracetamol and tramadol combination products to be added.	Formulary team	Complete
18/18	Agreed formulary entry for perindopril arginine to be added.	Formulary team	Complete
18/19	Current formulary entry for rubefacients to be replace with agreed updated entry.	Formulary team	Complete
18/20	E-pact data for rubefacients to be forwarded to Iain Roberts and Paul Foster	Formulary team	Complete
18/21	Accepted formulary entry for travel vaccines to be added.	Formulary team	Complete
18/22	Formulary entry for trimipramine to be added in line with discussion.	Formulary team	Complete
18/23	Liothyronine – feedback on discussion to Warwick Heale	Chris Roome	Outstanding
18/24	Nausea and vomiting in pregnancy and hyperemesis gravidarum to be brought back to FIG on completion of further work around the status and position within the treatment pathway, safety, the dose of ondansetron required and the cost.	Formulary Team	On agenda
18/25	Update agreed sections of the formulary migraine guidance in line with discussion.	Formulary team	Outstanding
18/26	Formulary guidance on the management of hypertension to be updated.	Formulary team	Complete
18/27	Review of NICE NG80 Asthma: diagnosis, monitoring and chronic asthma management to be added to the work plan.	Formulary team	Complete
18/28	MRHA Safety update: November 2017 – Add agreed information for Quinine	Formulary team	Complete
18/29	MRHA Safety update: November 2017 – Add agreed information for antiepileptic drugs.	Formulary team	Complete
18/30	MRHA Safety update: January 2018 – Add agreed entry for erythropoietins.	Formulary team	Complete