These minutes are in draft form until ratified by the committee at the next meeting on 20th April 2023.

Nottinghamshire Area Prescribing Committee Formulary Meeting Minutes

APC meeting 16th February 2023: the meeting took place as a web conference using Microsoft Teams.

All attendees should be aware that public authorities are legally required to comply with the Freedom of Information Act 2000. The minutes and papers from this meeting could be published on the Publication Scheme or internet with all names included unless notified to the Chair before the meeting commences or included in a pre-agreed confidential section due to the sensitive nature of the topic.

Present:

Laura Catt (LC) - Chair	**Prescribing Interface Advisor**	**NHS Nottingham & Nottinghamshire ICB**
David Kellock (DK)	**SFH Drug and Therapeutics Committee**	**Sherwood Forest Hospitals NHS Foundation Trust**
Steve Haigh (SH)	**Medicines Information Pharmacist**	**Sherwood Forest Hospitals NHS Foundation Trust**
Tim Hills (TH)	**Assistant Head of Pharmacy**	**Nottingham University Hospitals NHS Trust**
Jennifer Moss Langfield (JML)	**GP**	**LMC Representative**
Ann Whitfield (AW)	**Patient Representative**	
Katie Sanderson (KS)	**Patient Representative**	
Sue Haria (SuH) Representative in Jill Theobald's (JT) absence.	**Senior Medicines Optimisation Pharmacist**	**NHS Nottingham & Nottinghamshire ICB**
Hannah Godden (HG)	**Principal Pharmacist – Adult Mental Health Community Teams**	**Nottinghamshire Healthcare NHS Foundation Trust**
Gladys Maponese (GM) Representative in Georgie Dyson's (GD) absence.	**Medicines Management Pharmacist**	**Nottingham Urgent Treatment Centre, CityCare**

In Attendance:
Ahmed Gueffaf (AG) Rheumatology Pharmacist, Sherwood Forest Hospitals NHS Foundation Trust for the discussion about Shingles vaccine.
Emma Hallam (EH), Macmillan Consultant Radiographer, Nottingham University Hospital, for item 5a.
Dr Gillian Sare, Neurology Consultant, Nottingham University Hospital, for item 5b.

Observing:
Fiona Hutchinson, Pre-registration Pharmacist, Sherwood Forest Hospitals NHS Foundation Trust.

Interface Support (NHS Nottingham & Nottinghamshire ICB):
Lynne Kennell (LK), Specialist Interface & Formulary Pharmacist for SFH
Shary Walker (SW), Specialist Interface & Formulary Pharmacist
Irina Varlan (IV), Specialist Medicines Optimisation Interface Pharmacist
Vimbayi Mushayi (VM), Specialist Medicines Optimisation Interface Pharmacist
Nichola Butcher (NB), Specialist Medicines Optimisation Interface Pharmacist

1. Welcome and apologies

Apologies:
Jill Theobald (JT), Senior Medicines Optimisation Pharmacist, ICB
Tanya Behrendt (TB), Senior Medicines Optimisation Pharmacist, NHS Nottingham & Nottinghamshire ICB
Ankish Patel (AP), Head of PCN Workforce Nottingham & Nottinghamshire
Khalid Butt (KB), GP Prescribing Lead and LMC representative, Mid Notts PBP, Nottingham & Nottinghamshire ICB
Asifa Akhtar (AA), GP Prescribing Lead South Notts PBP, Nottingham & Nottinghamshire ICB
Mark Clymer (MC), Assistant Chief Pharmacist, Sherwood Forest Hospital NHS Foundation Trust
Georgie Dyson (GD), Advanced Clinical Practitioner, Nottingham Urgent Treatment Centre, CityCare
Deborah Storer (DS), Medicines Information Pharmacist, Nottingham University Hospitals NHS Trust
David Wicks (DW), GP Prescribing Lead Mid Notts PBP, Nottingham & Nottinghamshire ICB

To note: the meeting did not have a second GP and, therefore, was not quorate.

Post meeting note: a second GP has agreed all actions as per the minutes.

2. Declarations of interest

Agenda item 8: TH declared that a family member has hypothyroidism.
The other APC members and the APC support team made no declarations of interest.

3. Minutes of the last meeting

The minutes from the previous meeting were reviewed and accepted as an accurate record, subject to minor amendments.

4. Matters arising and action log

Melatonin: TH informed the committee that a business case has been submitted by NUH and is due to go to the Director of Finance meeting. There is currently no time frame, but this was being flagged for prioritising. Individual Trusts might be required to submit their own business cases.
IV advised the committee that she has submitted a request to the MHRA to consider reclassifying melatonin from a Prescription Only Medicine (POM) to a Pharmacy (P) medicine. The MHRA Scientific Advice Department have agreed to meet to discuss this.

Testosterone: The British Menopause Society (BMS) has updated its monitoring guidance. BMS now recommends monitoring total testosterone rather than the Free Androgen index. This will result in a minor amendment being made to the local guidelines.
ACTION: LK to update the prescribing information sheet.
March 2023: Updated prescribing information sheet emailed to APC members for ratification. Responses awaited.

Agomelatine: HG stated that both AST and ALT need to be monitored as per the Summary of Products Characteristics. This monitoring recommendation is already on the APC Agomelatine information sheet but does not state that both need to be specifically requested. LC updated the committee, saying that the SFH

lab has suggested that they can assist in the monitoring. John Lawton has been asked to follow the matter up with the other labs. The information sheet will be updated once clarification has been obtained.

ACTION: The interface team to highlight the need to request both AST and ALT specifically, via Hints and Tips.

March 2023: Action complete.

Doxazosin for PTSD: LK updated the committee, following a submission from an NUH neurologist for the off-label use for nightmares with post-traumatic stress disorder. Evidence is limited, consisting mainly of small open-label trials. LK had attempted to contact the armed forces about usage but had not obtained any information. No clinician support for the submission had been identified from Notts HCT. Clinicians from Sheffield Teaching Hospitals had indicated that it is not in use there for this condition.

Members discussed the most appropriate classification. Although there is limited published evidence to support its use in this off-label indication, the use of alpha-blockers for PTSD is noted in the Maudsley Guidelines. It was also acknowledged that this is a niche patient group for whom benefit is measurable and that there is widespread use of doxazosin already for other conditions in primary care. It was therefore agreed that doxazosin for nightmares associated with PTSD should be classified as AMBER 2. Primary Care prescribing should be requested only after efficacy and tolerability had been demonstrated. It was also requested that the specialist making the original submission collate patient numbers and audit feedback over a 12- month period.

ACTION: LK to advise the specialist and update the formulary. The follow-up audit to be added to the action log.

March 2023: Action complete.

Shingles vaccines for Rheumatology patients: AG attended from SFHT. LK explained that there had been previous APC discussions about this issue; it had since become apparent that a wider patient group than only rheumatology patients was affected and that other vaccines (varicella) are also involved. NHS England had confirmed that bone marrow transplant patients can receive the Shingrix® vaccine (see formulary amendments), but vaccination of other immunosuppressed patients was unresolved.

LK stated that BSR guidance advises that rheumatology patients should receive shingles and varicella vaccines before biologic commencement, whereas other specialities such as dermatology and gastroenterology vaccinate only against Varicella if non-immune. The inequity of this access was highlighted but it was understood to be due to differing speciality guidance.

Discussions had taken place in Secondary Care about the potential for these vaccinations to be given by the specialist service; however, there was not felt to be capacity for this and it would require patients to attend hospital for an additional appointment. It was also felt that Primary Care would be the more familiar setting for vaccinations. Conversely, requesting Primary Care to vaccinate patients may introduce delays to starting biologic therapy due to logistical issues with letters being actioned, the requirement to purchase vaccines and appointment availability. It was felt that Primary Care was not currently commissioned to offer vaccines outside Green Book recommendations, although it was understood that the cost of the vaccine could be reclaimed via an FP34 form.

The committee felt that the associated commissioning issues were beyond the scope of the APC. It was agreed that in the interim there would be no change to the formulary and that there should be a discussion with Rheumatology about administering these vaccines during a specialist clinic appointment.

ACTION: LK and LC to discuss this with the ICB Vaccination team and to flag to commissioners a potential gap in the service. AG to discuss this with the SFH rheumatology team.
March 2023: Update to be provided at April APC meeting.

Guanfacine: Classification will remain RED, due to issues outstanding over incorporating it into the Locally Enhanced Service.

5. New applications

a) **AS Saliva Orthana®** (Artificial Saliva): *Emma Hallam (EH), Macmillan Consultant Radiographer, attended at 14.30.*

SW presented the submission from an NUH consultant oncologist and a Macmillan consultant radiographer. The request was to add the medical device to the formulary and classify it as GREEN for xerostomia or dysphagia due to dry mouth. It is currently GREY on the formulary. The suggested place in therapy is as another treatment option, particularly in patients with some level of xerostomia or dysphagia due to dry mouth caused by late effects of radiotherapy treatment, as well as for those patients who have already tried other saliva substitutes but have found them to be ineffective or of negligible benefit, or when other saliva substitutes are unsuitable eg. due to acidic pH.

AS Saliva Orthana® oral spray comes in a 50 mL bottle and a 500 mL refill. It is pH neutral and a mucin-derived saliva substitute.

Evidence is limited but positive, suggesting that saliva preparations based on mucin have parameters similar to human saliva, delivering positive results and long-term relief periods and ranking significantly higher than the alternative.
However, due to the porcine derivative, this product is unsuitable for vegetarians and for people from certain religious groups. It was noted by APC that self-care and purchasing the spray over the counter may be appropriate for non-radiotherapy patients and should be highlighted on the formulary.

EH joined the meeting, stating that she advises post-radiotherapy patients to drink 10 mL prior to a meal to help with dysphagia and that the 500 mL refill would be beneficial for this use. However, no evidence was available to the committee to support this. EH added that this product has been found to be more beneficial to this cohort of patients than other artificial saliva products on the formulary. EH also added that use of the product is not only about eating but about improving the patient's quality of life too, giving a sense of normality to speech and relationships. AW commented that anything that makes a patient's life somehow akin to normal is positive. EH advised that not all patients need to use the product long-term post-radiotherapy and that they usually know after 2 years whether the patient requires it long-term. LK queried why the products on the formulary do not work. EH explained that pastilles need saliva to work, and gel often causes clogging in the mouth.

APC members agreed to classify the spray and refill as GREEN for all ACBS dry mouth conditions. A comment highlighting the environmental benefits of the refill, as well as information about the product being porcine-derived, will be added to the formulary. Due to lack of evidence, it was agreed that a submission would be made separately for using the product other than as an oral spray, eg by drinking 10 mL before meals.

ACTION: SW to update the formulary for both the spray and refill, including information on environmental benefits. Highlight via OptimiseRx that the product has a porcine derivative and to use the refill as a greener and more cost-effective option, but ensure that it is issued at appropriate intervals.
March 2023: Action complete.

Post meeting note- AS Saliva Orthana® is currently unavailable due to manufacturing supply issues.

b) **Melatonin for Huntington's Disease**: *Dr Gillian Sare, NUH Neurology Consultant, attended at 15:00.*

LK presented a submission for melatonin for sleep disorders in patients with Huntington's disease. An AMBER 2 classification had been requested. LK explained that melatonin was already on the formulary for use in selected groups of adult patients; it is approved for use in patients with learning disabilities and REM sleep disorders associated with Parkinson's disease, in line with NICE guidelines.

There is currently no published clinical trial evidence to support the use of melatonin specifically in Huntington's Disease, but a small trial is in progress. Anecdotally, melatonin has been found to be very helpful for this patient group and it is used in other centres that manage Huntington's Disease.

GS explained that the use of melatonin use would be limited as it is not appropriate at all stages of the disease; it is used for patients in the mid-stage, with either loss of circadian rhythm or who sleep very badly. Patient numbers would be low and the expectation is that these patients will not take melatonin indefinitely. It will be stopped once the sleep pattern settles and it is appropriate only for a proportion of the progression of their disease. Sleep disorders significantly affect the quality of life of both patients and carers, but it is not appropriate to use alternatives such as benzodiazepines or Z medicines in Huntington's disease, due to effects on cognition and the risk of falls. GS felt that these medicines are, in effect, contraindicated in this patient group.

JML felt it would be helpful to have an OptimiseRx message to highlight the risk of giving benzodiazepines and Z-medicines to these patients so that prescriptions are not issued in Primary Care without specialist involvement.

Although published evidence for the use of melatonin in Huntington's Disease was limited, it was agreed that, due to the potential for avoiding harm in this niche patient cohort which is under regular specialist review, melatonin should be classified as Amber 2. However, it was requested that the ongoing clinical trial data be reviewed once published.

ACTION: LK to amend formulary. Add to action log once trial evidence is published and review patient numbers in a year. OptimiseRx messages about benzodiazepines and Z drugs to be produced.
March 2023: Action complete.

6. Formulary amendments

a) For Information – Log of minor amendments carried out:

Noted and listed below:-

GREY

- **Spironolactone and furosemide 20mg/50mg capsules (Lasilactone®):** discontinued entry added on the formulary.
- **Dienogest 2mg film-coated tablets:** Zalkya® brand added to formulary entry.
- **Insuman Rapid, Basal and Comb insulin for injection:** products discontinued by the manufacturer. Added a note: "no new patient initiations; existing stocks can be used until exhausted, or until the patient is reviewed." Update diabetes guidelines.
- **Clarithromycin XL:** No particular benefit from once-a-day administration compared to twice a day.

RED

- **Paliperidone depot (Byannli®):** discussed at NottsHC TMOG; agreed RED as an option for specialist prescribing for carefully selected, stable patients who have had at least four injections of the 3-monthly paliperidone palmitate (Trevicta®) formulation, and where a 6-monthly injection is considered to offer a clear advantage.
- **Paliperidone depot (Trevicta®):** recommended for specialist prescribing in the formulary. Reclassification from Amber 2 as a RED classification is more appropriate.

AMBER 3

- **Mirabegron with solifenacin combination:** presented at the APC meeting in January 2023 and agreed by the committee to be reclassified from GREY to AMBER 3.

OTHER:

- **Smallpox:** amendment of the name "monkeypox" (Mpox) on the formulary, to reflect the Mpox (monkeypox) control; update UK 2022 strategy to 2023.
- **Methenamine hippurate (Hiprex®):** added as a cost-effective brand to be prescribed in Primary Care. OptimiseRx message enabled, and PPL updated.
- **Promethazine tablets (Phenergan®):** added as the preferred brand in Primary Care, due to a significant price difference. OptimiseRx message enabled and PPL updated.
- **Bydureon® BCise 2mg/0.85mL pre-filled pens:** change of presentation; formulary amended and diabetes guidelines updated.
- **Shingrix®:** NHS E has confirmed that, in individual cases, stem cell transplant patients aged 18 to 69 may receive Shingrix® vaccine (by PSD), using the national ImmForm stock pending an update to National Guidance and the Green Book.
- **Trurapi®/ Novorapid®:** formulary annotated to highlight Trurapi® as the first-choice insulin aspart product for new patients.
- **Testosterone gel:** hyperlink to MHRA alert "Topical testosterone risk of harm to children following accidental exposure" added.
- **Clozapine and constipation fact sheet:** link in the formulary updated to the most recent document produced by Nott HCT.
- **Sildenafil:** Archived DOH guidance removed.
- **Varenicline tartrate (Champix®):** currently unavailable because of a disruption in manufacturing; Information added to the formulary.

b) For discussion:

RED

- **Metolazone (Xaqua®):** currently classified GREY, pending further advice from MHRA about differences in bioequivalence between preparations. MHRA advice regarding switching from unlicensed to licensed preparation has now been published. Unlicensed preparation currently classified Red on the formulary.

ACTION: Refer to Trust DTC's. Confirm with NUH whether they still wish to pursue a reclassification to Amber 2.

March 2023: Update to be provided at April APC meeting.

AMBER 2

- **Uro-trainer® Polihexanide PHMB catheter irrigation solution:** for restricted patients on the catheter patency pathway. Microbiology advice had been sought and it was confirmed that there were no concerns about including this is in the formulary.
- **Anal irrigation systems (generic entry):** GREY entry for Peristeen® removed. Added generic anal irrigation system entry as AMBER 2 to the formulary, following recommendation and patient training by the continence specialist. Work is in progress to develop a formulary for these products.

OTHER:

- **Enoxaparin (Clexane®):** Secondary Care contract changes have resulted in a cost pressure from continued use of Inhixa® as enoxaparin brand of choice. Currently, Inhixa® is the brand of choice in Nottinghamshire and it was requested by SFH that this be reviewed. Inhixa® and Clexane® are priced as equivalent in Primary Care, so there are no price implications for Primary Care but potentially significant savings in Secondary Care. SFH are considering switching to Clexane®. The NUH position was TBC. It was suggested that the statement about brand of choice be removed, but highlight that different brands are available. Brand prescribing is needed to ensure that patients remain on their current brand, as devices are different.
  ACTION: LK to liaise with James Sutton (NUH) to confirm NUH position.
  LK to update formulary and Enoxaparin Guideline once situation confirmed.

March 2023: Update to be provided at April APC meeting.

- **Glandosane® spray:** long-term manufacturing problem; to remain non-formulary.

7. Horizon Scanning

GREY – no formal assessment

- **Melatonin 3mg tablet (Ceyesto®)**
- **Tozinameran 10 doses multi-dose vial (Comirnaty® 3micrograms/dose) ▼**: new formulation for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in infants and children aged 6 months to 4 years.
- **Tozinameran + famtozinameran (Comirnaty®▼ Original/Omicron BA.4/5) ▼**: for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals aged ≥5 years who have previously received at least a primary vaccination course against COVID-19. Licence change from use only in patients aged ≥12 years. Currently, this vaccine is not in the Nottinghamshire system.
- **Dapagliflozin tablets (Forxiga®):** licence update to include treatment of symptomatic chronic heart failure in adults. NICE TA is expected in June 2023.

OTHER:

- **Levomepromazine HCl 5mg/ml oral solution (Levorol®):** neuroleptic with various indications, particularly used in terminal illness. Add to action log to review once a price is available.
- **Anastrozole tablets:** now licensed for primary prevention of breast cancer in postmenopausal women at increased risk, as recommended in NICE CG164 (2017).
- **Latanoprost eye drops:** new benzalkonium chloride-free emulsion formulation. Add to action log for review once a price is available.

NEW PUBLICATION:

- Thyroid cancer: assessment and management – guidance (NG230) noted, no further action.

8. Liothyronine for hypothyroidism

LK updated members on the history of the current classification of liothyronine in the formulary. The position statement is due for review, and there have been local patient complaints that the statement does not reflect national guidance. Currently, there are approximately 23 patients prescribed liothyronine in Primary Care. Liothyronine prices have reduced significantly since the publication of the current position statement; it is now approximately £700 a year vs £4k a year, but is still significantly more expensive than levothyroxine.

National guidance via RMOC sanctions the use of liothyronine for patients who meet strict criteria and advises that prescriptions are continued under a shared care arrangement, if agreed by local commissioners. The local policy was written primarily for the purpose of reviewing current patients, but it advises that continued NHS prescription supported only in exceptional circumstances, on the recommendation from a NHS endocrinologist after a multidisciplinary discussion involving fellow consultants. This reflects RMOC guidance that not all clinicians may agree that a trial of liothyronine is warranted and that their clinical judgement must be recognised, given the evidence of the treatments. No requests to change this policy have been received from local endocrinologists and very few of the current patients had been initiated on treatment by a local endocrinologist. Therefore, it was not felt practical to develop a Shared Care Protocol.
The point was made during discussion that implementation of RMOC was not mandatory, but that a mechanism for ongoing prescribing should be available for patients in whom treatment is deemed appropriate. Currently, the position statement does not contain specific advice regarding new requests for treatment.

After discussion, the APC agreed that liothyronine should remain classified as GREY, but a statement should be added to the position statement about the acceptability of prescribing it in Primary Care for suitable patients. This would then align with national guidance ie patients may be prescribed it in Primary Care in exceptional circumstances, if at least two NHS endocrinologists have been involved in the decision to commence treatment. Monitoring requirements will also be added to the position statement.

LK asked the committee about continued use of the NHSE patient information leaflet, which currently has no logo or review date. AW agreed to help review the patient information leaflet.

ACTION: LK to review and update the liothyronine position statement for ratification. AW & LK to review the patient information leaflet.
March 2023: Updated position statement ratified at March APC. Patient information leaflet in development.

9. Amiodarone review supporting documents for Primary Care

NB presented the guidance, generated as a Primary Care document and ratified by the Senior Pharmacy Management Team earlier that month. NB explained that the request was to incorporate it as an appendix in the current APC Amiodarone Shared Care protocol.

NB advised that it had been developed by the ICB Medicine Safety team, following the MHRA alert in March 2022 and used the SCP as a basis. The guidance has been written in collaboration with Cardiology specialists by a Medicine Optimisation pharmacist who works as a clinical PCN pharmacist.

NB advised that the guidance supports Primary Care clinicians conducting reviews of patients prescribed amiodarone, to ensure that the SCP and all monitoring requirements are in place. The referral process for patients not currently on Shared Care has been agreed with Secondary Care. NB also advised that S1/EMIS F12 templates are being developed.

JML asked for it to be made clearer that a chest X-ray should be requested if a patient is experiencing respiratory symptoms. It was noted that work is ongoing regarding commissioning gaps for ECG monitoring in Primary Care and the need for an annual cardiology review.

The APC agreed to add this guidance as an appendix to the Amiodarone SCP.

ACTION: NB to update the SCP and upload it to the APC website.

March 2023: Action complete

10. Preferred Prescribing List

NB presented the PPL for information and explained that it is a Primary Care document advising on the preferred brands and formulations for prescribing within Primary Care, based on both cost-effective and safety considerations.

NB explained that the PPL is reviewed 6-monthly, is located on the medicine optimisation website, and the formulary is linked to this. It was reviewed and ratified by the ICB Medicine Optimisation and Governance Group in January 2023. The Joint formulary, the clinical system's formulary and OptimiseRx messages have been updated.

The main changes were summarised in the meeting papers. NB noted that the preferred brand of ethosuximide should be listed on the front sheet as Emeside®, not Esperi®. Details are correct in the PPL.

The APC noted the updated PPL.

ACTION: No further action is required.

11. Continence formulary update

SW presented the continence formulary, advising that it had been developed in collaboration with the continence specialists. The APC agreed to ratify the updated continence formulary. First-line products will be added as GREEN, to be prescribed after completion of a continence assessment. Second-line products will be added as AMBER 2, following a recommendation by a continence advisor and for existing patients. The APC approved the addition of catheter maintenance solutions to the formulary. Non-formulary products will not be GREY nor listed on the formulary. A note will be added advising that "Non-formulary continence products may be used in exceptional circumstances where none of the formulary options is suitable. Non-formulary continence products must be recommended and fitted by a continence advisor, and the reason must be documented in the patient's medical record".

ACTION: SW to feedback to JT for JT to upload to the website and amend the formulary.
March 2023: Action complete.

12. Any Other Business

SH requested assistance from committee members in carrying out a review of the topical antimicrobial section of the formulary, in particular of combination products with steroids.

JML suggested obtaining input from district nurses. TH advised that a new dermatology pharmacist at NUH may be available to support him, also suggesting asking for advice from Dr Viv Weston. SuH advised that she could forward details of Tissue Viability Leads (TVNs).

The meeting closed at 17:00.

Date of next APC Formulary meeting: Thursday, 20th April 2023 (2 pm – 5 pm, (MS Teams)

Date of next APC Guideline meeting: Thursday, 16th March 2023 (2 pm – 5 pm, (MS Teams)