



National Patient Group Direction (PGD)

Supply of Trimethoprim Tablets Version – 2.0

The purpose of the PGD is to allow management of acute uncomplicated urinary tract infection (UTI) in non-pregnant females aged 16 years and over, by registered pharmacists within Community Pharmacies.

This PGD authorises pharmacists delivering the NHS Pharmacy First Scotland Service Level Agreement to supply trimethoprim to non-pregnant females aged 16 years and over presenting with symptoms of an acute uncomplicated urinary tract infection (UTI) who meet the criteria for inclusion under the terms of the document.

Change History – see table at end of document for more details

Change to eligibility

1. Eligible age range – extended to 16 years and over
2. Haematuria – can now be considered for treatment in community pharmacy under certain circumstances (some exclusions still apply)
3. Diabetes – patients with diabetes can now be considered for treatment in community pharmacy
4. Symptoms of UTI lasting longer than 7 days – can now be considered for treatment in community pharmacy with guidance to report to GP practice
5. Breastfeeding – can now be considered for treatment in community pharmacy
6. Presence of vaginal discharge or itch – can now be considered for treatment unless “presence of new, unexplained vaginal discharge or itch suggestive of other pathology”

Clarification for community pharmacy network

7. Pregnancy – clarified to include those planning a pregnancy in next 3 months
8. Renal impairment – clarified as known “moderate to severe”
9. Folate deficiency – clarified as known folate deficiency “which has not been corrected”
10. Hepatic insufficiency – clarified as “severe known liver fibrosis / encephalopathy”
11. Immunosuppressed – clarified as “current immunosuppression e.g. chemotherapy, long term oral corticosteroids, other immunosuppressant therapies

If this PGD is past the review date, the content shall remain valid until such time that the review is complete and a new version has been published. **It is the responsibility of the person using the PGD to ensure they are using the most recent issue.**

PGD Trimethoprim Tablets

Authorisation

This specimen PGD has been produced in collaboration with the Scottish Antimicrobial Prescribing Group and the Primary Care Community Pharmacy Group to assist NHS Boards in the provision of uniform services under the 'NHS Pharmacy First Scotland' banner across NHS Scotland. NHS boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may supply trimethoprim tablets under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct, and to ensure familiarity with the marketing authorisation holder's summary of product characteristics (SPC) for all medicines supplied in accordance with this PGD.

NHS board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Supply of the medicine has to be by the same practitioner who has assessed the patient under the PGD.

This specimen PGD has been approved on behalf of NHS Scotland by NHS 24 by:

Doctor	Dr Laura Ryan	Signature	<u>Signed by Laura Ryan</u>
Pharmacist	Dr John McAnaw	Signature	<u>Signed by John McAnaw</u>
NHS Scotland Representative	Mr Jim Miller	Signature	<u>Signed by Jim Miller</u>

Approved on behalf of NHS Forth Valley by:

Medical Director Murray	Andrew Murray	Signature	<u>Signed by Andrew</u>
Director of Pharmacy	Laura Byrne	Signature	<u>Signed by Laura Byrne</u>
Interim Director of Nursing	Gillian Morton	Signature	<u>Signed by Gillian Morton</u>
Date Approved	7 September 2022		
Effective from	<u>August 2022</u>	Review Date	<u>August 2024</u>

Clinical Situation

Indication	Acute uncomplicated urinary tract infection (UTI) in non-pregnant females aged 16 years and over.
Inclusion Criteria	<p>Non-pregnant females, assigned as female at birth who have not had any reassignment procedures, aged 16 years and over.</p> <p>Older women should be fit, ambulatory and self-caring.</p> <p>If no dipstick testing available or over 65 years of age, patient must present with three or more of the following symptoms:</p> <ul style="list-style-type: none">• Dysuria• Frequency• Urgency• Suprapubic tenderness• or BOTH dysuria and frequency are present. <p>Otherwise:</p> <p>Diagnose a UTI in the presence of two or more urinary symptoms (dysuria, frequency, urgency, visible haematuria or nocturia) and a positive dipstick test result for nitrite.</p> <p>Note: A positive dip stick in women over 65 is not an indication of UTI as asymptomatic bacteriuria is common in older women.</p>

Exclusion Criteria

- Patients assigned as male at birth
- Patients under 16 years
- Patients living in long term care facilities
- Allergy or serious adverse effect from co-trimoxazole, trimethoprim or to any other components of the medication
- If **upper** urinary tract infection is more likely i.e. flank pain radiating towards the groin, feel systemically unwell (fever and chills, rigors, nausea, vomiting), as well as with other symptoms of lower UTI. (Patients presenting with such symptoms should be urgently referred to GP/OOH)
- Patients over 45 years with unexplained visible haematuria without symptoms of UTI
- Visible haematuria which persists or recurs after successful treatment of UTI
- Unexplained non-visible haematuria if found on urine dipstick if no UTI symptoms present
- Patients over 40 years who present with recurrent UTI with any haematuria
- Risk of treatment failure due to one or more of the following:
Received antibiotic treatment for UTI within 1 month; 2 or more UTI episodes in the last 6 months or 3 or more episodes in the last 12 months; taking antibiotic prophylaxis for recurrent UTI
- Presence of new unexplained vaginal discharge or itch suggestive of other pathology
- Confused
- Patient utilises urethral or suprapubic catheters (either indwelling or intermittently)
- Known abnormality of the urinary tract
- Pregnancy – known or suspected (and including those intending to become pregnant within the next 3 months)
- Known moderate to severe renal impairment (where pharmacists are able to independently access relevant patient records/blood results e.g. via Clinical Portal to establish levels of renal impairment when required, a supply of treatment can be considered. If this is not possible, patient should be referred to GP/OOH)
- Known haematological abnormalities, porphyria/known folate deficiency which has not been corrected
- Known severe known liver fibrosis/encephalopathy (where pharmacists are able to independently access relevant patient records/blood results e.g. via Clinical Portal to establish levels of hepatic impairment when required, a supply of treatment can be considered. If this is not possible, patient should be referred to GP/OOH.)
- Known hyperkalaemia, megaloblastic anaemia, galactose intolerance, the Lapp lactose deficiency or glucose-galactose malabsorption
- Current immunosuppression e.g. chemotherapy, long term oral corticosteroids, other immunosuppressant therapies
- Taking any medication which interacts with trimethoprim – refer to BNF for full list of interactions
- Decline to provide consent or non-capacity to consent.

<p>Cautions /Need for further advice/ Circumstances when further advice should be sought from a doctor</p>	<p>Any doubt as to inclusion/exclusion criteria being met.</p> <p>Patient over 65 years</p> <ul style="list-style-type: none"> • Manage suspected UTI in ambulant women aged 65 years and over who are able to look after themselves independently with no comorbidities as in those aged under 65 years, taking into account the increasing background incidence of asymptomatic bacteriuria. <p>Diabetes</p> <ul style="list-style-type: none"> • Patients with known diabetes are not excluded from treatment from community pharmacy. If concerned about recurrent UTIs or that this may be a side effect of medication e.g. SGLT2 inhibitors, please consider signposting for GP practice follow up. <p>Symptoms of UTI lasting longer than 7 days</p> <ul style="list-style-type: none"> • Prolonged symptoms suggestive of a UTI may be considered for treatment, but clinical judgement may be required regarding onward referral. <p>Breastfeeding</p> <ul style="list-style-type: none"> • Patients who are breastfeeding and displaying symptoms of UTI can be considered for treatment in community pharmacy • As a general rule, if a medication is licensed for use in paediatrics (neonatal age onward) then it should be safe for use in breastfeeding as the dose the infant/child receives via the breastmilk will be significantly less than therapeutic doses. • National Institute for Health and Care Excellence. <i>British National Formulary for Children</i>. Available at TRIMETHOPRIM Drug BNF content published by NICE (accessed 20th January 2022) - Trimethoprim is licensed for use in the neonatal period onwards. • UK Drugs in Lactation Service states the following: <ul style="list-style-type: none"> ○ Trimethoprim can be used with caution. ○ Limited published evidence of safety, small amounts in breast milk, for short-term use only due to risk of folate deficiency, monitor infant for gastro-intestinal disturbances and oral candida infection, especially if used in high doses, although these effects are unlikely to occur. ○ Available at: Trimethoprim – Medicines – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice (accessed 20th January 2022)
<p>Action if Excluded</p>	<p>Refer to GP Practice/Out-of-hours service and document in Patient Medication Record (PMR)</p>

Action if Patient Declines	<p>Note that self-care should be considered as an option depending on symptom severity.</p> <p>If patient declines treatment, advise on self-care to relieve symptoms and advise to return to pharmacy if symptoms fail to resolve within 3 days or if symptoms worsen.</p> <p>Patients can be directed to NHS Inform for guidance on self-care at: Urinary tract infection (UTI) - Illnesses & conditions NHS inform (accessed 20th January 2022)</p> <p>The reason for declining treatment and advice given must be documented.</p> <p>Ensure patient is aware of risks and consequences of declining treatment. Record outcome in Patient Medication Record (PMR) if appropriate.</p>
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Description of Treatment

Name of Medicine	Trimethoprim
Form/Strength	200 mg (or 2 x 100 mg) Tablets
Route of administration	Oral
Dosage	200 mg
Frequency	Twice a day (12 hourly)
Duration of treatment	3 days
Maximum or minimum treatment period	Maximum 3 days (1200 mg)
Quantity to supply/administer	6 x 200 mg tablets or 12 x 100 mg tablets
Black triangle (▼) additional monitoring required	No
Legal Category	POM (Prescription Only Medicine)
Is the use outwith the SPC	No
Storage requirements	As per manufacturer's instructions Store below 25°C in a cool dry place
Additional information	None

<p>Warnings including possible adverse reactions and management of these</p>	<p>The most frequent adverse effects at usual dose are pruritus and skin rash (in about 3 to 7% of patients). These effects are generally mild and quickly reversible on withdrawal of the drug.</p> <p>For a full list of side effects – refer to the marketing authorisation holder’s Summary of Product Characteristics (SPC). A copy of the SPC must be available to the health professional administering medication under this Patient Group Direction. This can be accessed on www.medicines.org.uk</p>
<p>Reporting procedure for adverse reactions</p>	<p>Pharmacists should document and report all adverse incidents through their own internal governance systems.</p> <p>All adverse reactions (actual and suspected) should be reported to the appropriate medical practitioner and recorded in the patient’s medical record. Pharmacists should record in their PMR and inform the patient’s GP as appropriate.</p> <p>Where appropriate, use the Yellow Card System to report adverse drug reactions. Yellow Cards and guidance on its use are available at the back of the BNF or online at http://yellowcard.mhra.gov.uk/</p>

Advice to Patient/carer including written information

- Advise patient about the importance of hydration in relieving symptoms.
- Offensive smelling urine/cloudy – may be suggestive of dehydration
- Increasing fluid intake to around 2.5 L per day (6-8 mugs containing approximately 350 ml) is thought to reduce UTI by dilution and flushing of bacteriuria. (While no evidence was identified for benefit, increasing fluid intake with water in women with urinary symptoms is a low-cost intervention without evidence of harm that may provide symptomatic relief)
Provide a cystitis/UTI patient information leaflet and discuss contents with patients. [Cystitis- Patient Leaflet | BMJ Best Practice](#) (accessed 2nd May 2022)
The patient information leaflet contained in the medicine should be made accessible to the patient. Where this is unsuitable, sufficient information should be given to the patient in a language that they can understand.
- Inform patient of possible side effects and their management and who to contact should they become troublesome.
- Explain the benefits and risks of taking antibiotics for this condition.
- If on combined oral contraception, no additional contraceptive precautions are required unless vomiting or diarrhoea occur. (See reference section for Faculty of Reproductive and Sexual Healthcare Guidance)
- Advise patient of self-management strategies including maintaining a good fluid intake, wearing loose fitting underwear/clothing, wearing cotton underwear and avoidance of vaginal deodorants.
- Advise patient on ways to prevent re-infection – e.g. double voiding, voiding after sexual intercourse.
- Paracetamol and ibuprofen may relieve dysuric pain and discomfort.
- Ensure patient is aware that if symptoms worsen, they experience significant flank pain, become systemically unwell, or develop a fever, then they should seek medical advice that day.
- Advise patient to seek further medical advice, if symptoms do not resolve after 3 days, if symptoms return or drug side effects are severe.
- Advise patient with haematuria which persists or recurs after successful treatment of UTI to seek further medical advice for follow up.
- Advise patient to discontinue treatment if rash develops and seek medical advice.
- Advise patient that their GP will be informed the next working day that antibiotics have been supplied or appropriate referral has been made.
- Advise patient that if they require to seek further advice from the Out-of-hours service they should make staff aware of their trimethoprim treatment. Information on medicines can be found at <https://www.medicines.org.uk/emc/browse-medicines> or <https://www.gov.uk/pil-spc>

Monitoring	Not applicable
Follow-up	Not applicable
Additional Facilities	The following should be available where the medication is supplied: <ul style="list-style-type: none"> • An acceptable level of privacy to respect patient's right to confidentiality and safety. • Access to medical support (this may be via the telephone). • Approved equipment for the disposal of used materials. • Clean and tidy work areas, including access to hand washing facilities. • Access to current BNF (online version preferred).

Characteristics of staff authorised under the PGD

Professional qualifications	Registered pharmacist with current General Pharmaceutical Council (GPhC) registration. <i>Under PGD legislation there can be no delegation. Supply of the medication has to be by the same practitioner who has assessed the patient under this PGD.</i>
Specialist competencies or qualifications	Has successfully completed NES Pharmacy e-learning module on "Urinary Tract Infections for NHS Pharmacy First Scotland". https://learn.nes.nhs.scot/33556/pharmacy/cpd-resources/urinary-tract-infections-uti-for-nhs-pharmacy-first-scotland Able to assess the person's capacity to understand the nature and purpose of the medication in order to give or refuse consent. Must be familiar with the trimethoprim Summary of Product Characteristics (SPC).
Continuing education and training	Has read current guidance on the management of urinary tract infections e.g. PHE/NICE, SIGN, SAPG Health Improvement Scotland. <i>SIGN 160: Management of suspected bacterial lower urinary tract infection in adult women. A national clinical guideline.</i> September 2020. Available at sign-160-uti-0-1_web-version.pdf (accessed 20 th January 2022) Health Improvement Scotland: Scottish Antimicrobial Prescribing Group (SAPG). <i>Urinary Tract Infections.</i> Available at: Urinary tract infections (sapg.scot) (accessed 20 th January 2022) Aware of local treatment recommendations. Attends approved training and training updates as appropriate. Undertakes CPD when PGD or NES Pharmacy module updates.

Audit Trail

Record/Audit Trail	<p>All records must be clear, legible and in an easily retrieval format. Pharmacists must record in Patient Medication Record (PMR)</p> <p>The following records should be kept (paper or computer based) and are included in the patient assessment form:</p> <ul style="list-style-type: none"> • Patient's name/parent/guardian/person with parental responsibility, address, date of birth and consent given • Patient's CHI number • Contact details of GP (if registered) • Presenting complaint and diagnosis • Details of medicine supplied • The signature and printed name of the healthcare professional who supplied the medicine. • Advice given to patient (including side effects) • The patient group direction title and/or number Whether the patient met the inclusion criteria and whether the exclusion criteria were assessed • Details of any adverse drug reaction and actions taken including documentation in the patient's medical record • Referral arrangements (including self-care) <p><i>The patient's GP, where known, should be provided with a copy of the GP notification form for the supply of trimethoprim or appropriate referral on the same, or next available working day.</i></p> <p>These records should be retained in accordance with national guidance¹ (see page 56 for standard retention periods summary table). Where local arrangements differ, clarification should be obtained through your Health Board Information Governance Lead.</p> <p>All records of the drug(s) specified in this PGD will be filed with the normal records of medicines in each service. A designated person within each service will be responsible for auditing completion of drug forms and collation of data.</p> <p>1. Scottish Government. <i>Scottish Government Records Management</i>. Edinburgh 2020. Available at SG-HSC-Scotland-Records-Management-Code-of-Practice-2020-v20200602.pdf (Accessed on 29th November 2021)</p>
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Additional references	<p>British National Formulary (BNF) current edition</p> <p>Electronic Medicines Compendium. <i>Trimethoprim SPC</i>. Available at Home - electronic medicines compendium (emc) (accessed 2nd May 2022)</p> <p>National Institute for Clinical Excellence / Public Health England. <i>Summary of antimicrobial prescribing guidance – managing common infections</i>. Jan 2022. Available at: Antimicrobial prescribing table (bnf.org) (accessed 24th February 2022)</p> <p>Public Health England. <i>Diagnosis of urinary tract infections</i>.</p>
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	<p>October 2021. Available at: Diagnosis of urinary tract infections - quick reference tool for primary care (publishing.service.gov.uk) (accessed 24th February 2022)</p> <p>Royal College of General Practitioners. <i>TARGET Urinary tract infection resource suite</i>. Available at: Urinary tract infection resource suite: Patient facing materials (rcgp.org.uk) (Accessed 24th February 2022)</p> <p>Health Protection Scotland. Scottish Urinary Tract Infection Network. Available at: HPS Website - Scottish Urinary Tract Infection Network (accessed 24th February 2022)</p> <p>Faculty of Sexual and Reproductive Health - Jan 2019 https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/fsrh-guidance-drug-interactions-hormonal-contraception-jan-2019.pdf (Accessed on 23rd February 2022)</p>
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Version history

Version	Date	Summary of Changes
1.0	March 2020	Version 1.0 Original PGD
2.0	August 2022	<p>The following sections have been updated:</p> <ul style="list-style-type: none"> • Addition of covering statement regarding validity of PGD when approaching date for review of content • Indication <ul style="list-style-type: none"> ○ Removal of upper age limit • Inclusion criteria <ul style="list-style-type: none"> ○ Clarification that “older women should be fit, ambulatory and self-caring” and that “a positive dip stick in women over 65 is not an indication of UTI as asymptomatic bacteriuria is common in older women.” ○ Inclusion of visible haematuria in list of symptoms when testing urine with dipstick • Exclusion criteria <ul style="list-style-type: none"> ○ Upper age limit removed ○ Clarification that patients living in long term care facilities are excluded ○ Clarification of definition of “upper” UTI ○ Haematuria – specific criteria now apply ○ Clarification of definition of vaginal discharge/itch ○ Clarification of catheter use ○ Pregnancy – now includes women who intend to become pregnant in next 3 months ○ Clarification of definition and associated actions required for patients with renal or hepatic impairment ○ Clarification of definition of immunosuppression • Cautions/further advice <ul style="list-style-type: none"> ○ Removal from exclusion, insertion into cautions/further advice with provision of additional information for patients over 65 years, with diabetes, symptoms lasting more than 7 days, breastfeeding • Advice to patient <ul style="list-style-type: none"> ○ Update to information for patients • Action if patient is excluded <ul style="list-style-type: none"> ○ Removal of requirement to record in Pharmacy Care Record (PCR) • Action if patient declines <ul style="list-style-type: none"> ○ Inclusion of link to NHS Inform for guidance on self-care ○ Removal of requirement to record in PCR • Specialist competencies or qualifications <ul style="list-style-type: none"> ○ Updated link to training module • Record/audit trail <ul style="list-style-type: none"> ○ Removal of requirement to record in PCR ○ Clarification that notification form should be sent to GP for patients being referred as well as those being treated by community pharmacy. ○ Update to information on retention of records ○ Update to additional references

PATIENT GROUP DIRECTION FOR THE SUPPLY OF TRIMETHOPRIM BY COMMUNITY PHARMACISTS UNDER THE “NHS PHARMACY FIRST SCOTLAND” SERVICE

Individual Authorisation

PGD does not remove inherent professional obligations or accountability

It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with the General Pharmaceutical Council Standards for Pharmacy Professionals.

Note to Authorising Authority: authorised staff should be provided with access to the clinical content of the PGD and a copy of the document showing their authorisation.

I have read and understood the Patient Group Direction authorised by each of the individual NHS Boards that I wish to operate in and agree to provide Trimethoprim tablets.

Name of Pharmacist

GPhC Registration Number

Normal Pharmacy Location

(Only one Pharmacy name and contractor code is required for each Health Board (HB) area where appropriate. If you work in more than 3 HB areas please use additional forms.)

Name & Contractor code HB (1)

Name & Contractor code HB (2)

Name & Contractor code HB (3)

Please indicate your position within the pharmacy by ticking one of the following:

Locum Employee Manager Owner

Signature _____ Date _____

Please tick and send to each Health Board you work in. Fax numbers, email and postal addresses are given overleaf.

Ayrshire & Arran	<input type="checkbox"/>	Grampian	<input type="checkbox"/>	Orkney	<input type="checkbox"/>
Borders	<input type="checkbox"/>	Gr Glasgow & Clyde	<input type="checkbox"/>	Shetland	<input type="checkbox"/>
Dumfries & Galloway	<input type="checkbox"/>	Highland	<input type="checkbox"/>	Tayside	<input type="checkbox"/>
Fife	<input type="checkbox"/>	Lanarkshire	<input type="checkbox"/>	Western Isles	<input type="checkbox"/>
Forth Valley	<input type="checkbox"/>	Lothian	<input type="checkbox"/>		

NHS Board	Address	Fax Number
Ayrshire & Arran	Iain Fulton, NHS Ayrshire & Arran, Eglington House, Ailsa Hospital, Dalmellington Road, Ayr, KA6 6AB margaret.scott3@aapct.scot.nhs.uk	Please email or post
Borders	Adrian Mackenzie, Lead Pharmacist Pharmacy Department, Borders General Hospital, Melrose, TD6 9BS communitypharmacy.team@borders.scot.nhs.uk	Please email or post
Dumfries & Galloway	NHS Dumfries & Galloway, Primary Care Development, Ground Floor North, Mountainhall Treatment Centre, Bankend Rd, Dumfries, DG1 4TG Dg.pcd@nhs.scot	Please email or post
Fife	PGD Administrator, Pharmacy Services, NHS Fife, Pentland House, Lynebank Hospital, Halbeath Road, Dunfermline, KY11 4UW Fife.pgd@nhs.scot	Please email or post
Forth Valley	Community Pharmacy Development Team, Forth Valley Royal Hospital, Stirling Road, Larbert, FK5 4WR fv.communitypharmacysupport@nhs.scot	Please email or post
Grampian	Pharmaceutical Care Services Team NHS Grampian, Pharmacy & Medicines Directorate, Westholme, Woodend, Queens Road, Aberdeen, AB15 6LS gram.pharmaceuticalcareservices@nhs.scot	Please email or post
Greater Glasgow & Clyde	Janine Glen, Contracts Manager, Community Pharmacy, NHS Greater Glasgow & Clyde, Clarkston Court, 56 Busby Road, Glasgow G76 7AT ggc.cpdevteam@nhs.scot	0141 201 6044 Or email
Highland	Community Pharmaceutical Services, NHS Highland, Assynt House, Beechwood Park, Inverness. IV2 3BW nhsh.cpsoffice@nhs.scot	Please email or post
Lanarkshire	Pharmacy/Prescribing Admin Team, NHS Lanarkshire Headquarters, Kirklands, Fallside Road, Bothwell, G71 8BB Pharmacy.AdminTeam@lanarkshire.scot.nhs.uk	Please email or post
Lothian	Primary Care Contractor Organisation, 2 ND Floor, Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG CommunityPharmacy.Contract@nhslothian.scot.nhs.uk	Please email or post
Orkney	Lyndsay Steel, Lead General Practice Pharmacist. The Balfour, Foreland Road, Kirkwall, KW15 1NZ Phone: 01856 888 911 ork.primarycarepharmacy@nhs.scot	Please email or post
Shetland	Mary McFarlane, Principle Pharmacist, NHS Shetland, Gilbert Bain Hospital, Lerwick, Shetland, ZE1 0TB	01595 743356
Tayside	Diane Robertson Pharmacy Department, East Day Home, Kings Cross Hospital, Clepington Road, Dundee, DD3 8AE Diane.Robertson9@nhs.scot	Please email or post
Western Isles	Michelle Taylor, Primary Care Dept, The Health Centre, Springfield Road, Stornoway, Isle of Lewis, HS1 2PS	Please post