Patient Group Direction for the administration and/or supply of Fluconazole 150mg capsules to named patients registered with the Minor Ailment Service attending community pharmacies in NHS Borders.

This document authorises the administration and/or supply of Fluconazole 150mg capsules by Pharmacists to named patients registered with the Minor Ailment Service who meet the criteria for inclusion under the terms of the document.

The pharmacist seeking to supply and/or administer Fluconazole 150mg capsules must ensure that all clients have been screened and meet the criteria before supply takes place.

The purpose of this Patient Group Direction is to allow management of the supply of the prescription only medicine pack of Fluconazole 150mg capsules on the Minor Ailment Service.

PGD previously approved: November 2010

This direction was authorised on: February 2016

The direction will be reviewed by: February 2018

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Clinician Responsible for Training and Review: Lead Pharmacist – Community and Social Care

PGD reviewed by: Elaine Hancock, Prescribing Support Pharmacist and Independent Prescriber in Sexual Health and Dr Ailsa Wylie, Clinical Lead in Family Planning

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1. This Patient Group Direction relates to the following specific preparation:

Name of medicine, Strength, Formulation	Fluconazole 150mg capsules **(note: this is NHSB formulary second choice: Clotrimazole should be actively excluded as first choice)**
Legal status	POM Prescription Only Medicine
Storage	Store below 30ºC
Dose	Vaginal candidiasis – a single dose of 150mg by mouth
Route/method	Oral
Frequency	One capsule completes the course.
Total dose Quantity (Maximum/Minimum)	One capsule of 150mg Fluconazole.
Advice to Patients	Provide Patient Information Leaflet. Treat at any time of menstrual cycle, including during periods. Discuss any possible side effects with the patient. Advise regarding re-infection and that partner may need treatment if symptomatic. Washing the vaginal area with water only, avoiding the use of perfumed soaps, vaginal deodorants or douches. Avoiding using latex condoms, spermicidal creams and lubricants if they cause irritation. Wearing cotton underwear and loose-fitting clothes if possible.

Follow up Arrangements Relevant Warnings	If symptoms are not resolved within three days the patient should consult with their GP. Adverse Reactions Occasional : nausea, abdominal discomfort, diarrhoea, flatulence, headache, rash Rare: dyspepsia, vomiting, taste disturbance, hepatic disorders, hypersensitivity reactions, anaphylaxis, dizziness, seizures, alopecia, pruritus, toxic epidermal necrolysis, Stevens-Johnston syndrome, hyperlipidaemia, leucopoenia, thrombocytopenia, hypokalaemia.

2. Clinical condition

Clinical Condition to be treated	Candidiasis is a yeast infection caused by the Candida species of fungus, usually Candida albicans. Many women are affected by vaginal thrush at some point in their lives and in some women it may recur regularly. The condition develops when Candida albicans, which is often present in the vagina, a white non smelling vaginal discharge; vaginal itching or soreness; vulval itching, soreness or redness.
Criteria for inclusion	Woman with previous history of vaginal candidiasis presenting in Community Pharmacy with a need for treatment of symptoms of vaginal candidiasis, and registered for the Minor Ailment Service (MAS).
Criteria for exclusion	Patient not participating in MAS. Under 16 and over 60 years of age. Pregnancy or risk of pregnancy. For further guidance please see manufacturer's SPC. Breast feeding Known allergy to Fluconazole. Liver and kidney disease. Known diabetes mellitus Known human immunodeficiency virus (HIV) infection Known recurrent VVC, diagnosis of VVC twice or more in the last 6 months, or treatment for VVC in the last 3 months.

	Patient with genital ulcers or skin conditions affecting the genitalia. Patient complaining of other symptoms. Patient using any drug with a potentially hazardous interaction with Fluconazole, as indicated in the current British National Formulary (BNF). Reservation/concerns by patient about the side effects of the antifungal preparation.
Action if excluded	Refer to GP Routine referral should also be expected if: If symptoms not clearing within 3 days Pregnant Breast feeding Renal impairment Known diabetic and recurring candidiasis Second request within one month Vaginal pain, bleeding or blistering If at risk of pregnancy as described above manage patient appropriately for candidasis and pregnancy risk.
Action if declines	Document refusal in PMR and if patient declines alternatives refer to the GP.
Interactions with other medicaments and other forms of interaction	The following drug interactions relate to the use of multiple-dose fluconazole, and the relevance to single-dose fluconazole has not yet been established: **Anticoagulants** In an interaction study, fluconazole increased the prothrombin time (12%) after warfarin administration in healthy males. In post-marketing experience, as with other azole antifungals, bleeding events (bruising, epistaxis, gastrointestinal bleeding, haematuria and melaena) have been reported in association with increases in prothrombin time in patients receiving fluconazole concurrently with warfarin. Prothrombin time in patients receiving coumarin-type anticoagulants should be carefully monitored. **Benzodiazepines (Short acting)** Following oral administration of midazolam, fluconazole resulted in substantial increases in midazolam concentrations and psychomotor effects.

	This effect on midazolam appears to be more pronounced following oral administration of fluconazole than with fluconazole administered intravenously. If concomitant benzodiazepine therapy is necessary in patients being treated with fluconazole, consideration should be given to decreasing the benzodiazepine dosage and the patients should be appropriately monitored. **Sulphonylureas** Fluconazole has been shown to prolong the serum half-life of concomitantly administered oral sulphonylureas (chlorpropamide, glibenclamide, glipizide and tolbutamide) in healthy volunteers. Fluconazole and oral sulphonylureas may be co-administered to diabetic patients, but the possibility of a hypoglycaemic episode should be borne in mind. **Hydrochlorothiazide** In a kinetic interaction study, co-administration of multiple-dose hydrochlorothiazide to healthy volunteers receiving fluconazole increased plasma concentrations of fluconazole by 40%. An effect of this magnitude should not necessitate a change in the fluconazole dose regimen in subjects receiving concomitant diuretics, although the prescriber should bear it in mind. **Phenytoin** Concomitant administration of fluconazole and phenytoin may increase the levels of phenytoin to a clinically significant degree. If it is necessary to administer both drugs concomitantly, phenytoin levels should be monitored and the phenytoin dose adjusted to maintain therapeutic levels. **Rifampicin** Concomitant administration of fluconazole and rifampicin resulted in a 25% decrease in the AUC and 20% shorter half-life of fluconazole. In patients receiving concomitant rifampicin, an increase in the fluconazole dose should be considered. **Ciclosporin** A kinetic study in renal transplant patients found fluconazole 200 mg daily to slowly increase ciclosporin concentrations. However, in another multiple dose study with 100 mg daily, fluconazole did not affect ciclosporin levels in patients with bone marrow transplants. Ciclosporin plasma concentration monitoring in patients receiving fluconazole is recommended.

	Theophylline In a placebo controlled interaction study, the administration of fluconazole 200 mg for 14 days resulted in an 18 % decrease in the mean plasma clearance of theophylline. Patients who are receiving high doses of theophylline or who are otherwise at increased risk for theophylline toxicity should be observed for signs of theophylline toxicity while receiving fluconazole, and the therapy modified if signs of toxicity develop. **Zidovudine** Two kinetic studies resulted in increased levels of zidovudine most likely caused by the decreased conversion of zidovudine to its major metabolite. One study determined zidovudine levels in AIDS or ARC patients before and following fluconazole 200 mg daily for 15 days. There was a significant increase in zidovudine AUC (20 %). A second randomised, two-period, two-treatment cross-over study examined zidovudine levels in HIV infected patients. On two occasions, 21 days apart, patients received zidovudine 200 mg every eight hours either with or without fluconazole 400 mg daily for seven days. The AUC of zidovudine significantly increased (74 %) during co-administration with fluconazole. Patients receiving this combination should be monitored for the development of zidovudine-related adverse reactions. **Rifabutin** There have been reports that an interaction exists when fluconazole is administered with rifabutin, leading to increased serum levels of rifabutin. There have been reports of uveitis in patients to whom fluconazole and rifabutin were co-administered. Patients receiving the two concomitantly should be carefully monitored. **Tacrolimus** There have been reports of an interaction when fluconazole is given concomitantly with tacrolimus, leading to increased serum levels of tacrolimus. There have been reports of nephrotoxicity in patients to whom fluconazole and tacrolimus were co-administered. Patients receiving the two concomitantly should be carefully monitored.

3. Records-A CP2 form should be generated and the consultation recorded on the Pharmacy PMR

1. **The following records should be kept (either paper or computer based)**
   The GP practice
   The patient name and CHI number
   The medicine name, dose, route, time of dose(s), and where appropriate, start date, number of doses and or period of time, for which the medicine is to be supplied or administered
   The signature and printed name of the approved healthcare professional who supplied or administered the medicine
   Whether patient met the inclusion criteria and whether the exclusion criteria were assessed
   Quantity supplied / received and current stock balance

2. **Preparation, audit trail, data collection and reconciliation**-
   Stock balances should be reconcilable with Receipts, Administration, Records and Disposals on a patient by patient basis.

3. **Storage**- Store below 30ºC

4. **Professional Responsibility -**
   - ❖ All Health Professionals will ensure he/she has the relevant training and is competent in all aspects of medication, including contra-indications and the recognition and treatment of adverse effects. He/she will attend training updates as appropriate.
   - ❖ Pharmacist must be registered with the GPhC and contracted to provide the Minor Ailment Service.
   - ❖ Sources of Evidence used for the PGD creation should be stated

5. References

- ❖ British National Formulary (BNF) current edition
  https://www.medicinescomplete.com/mc/

- ❖ Borders Joint Formulary (BJF)
  http://intranet/new_intranet/microsites/index.asp?siteid=65&uid=1

- ❖ SPC
  www.medicines.org.uk

Patient Group Direction For Provision of Fluconazole 150mg capsule by Pharmacists providing the Minor Ailment Service in NHS Borders

This Patient Group Direction is Approved for use by the under-signed :			
Job Title	**Name**	**Signed**	**Date**
Interim Senior Doctor/Dentist for relevant clinical area	~~Cliff Sharp~~ ANDREW MURRAY MEDICAL DIRECTOR		1/4/16
NHS Borders Director of Pharmacy	Alison Wilson		30/3/16
NHS Borders Senior Health Professional for Clinical Area	~~Evelyn Rodger~~ NICKY BERRY		8/4/16

PGD AUTHORISED ON ..8../..4../..16.. BY NHS BORDERS ADTC/CHAIRPERSON

Signed by ADTC CHAIRPERSON: .....

Name: Karen McNicoll.....

The Health Professionals named below, being contractors of NHS Borders based at.....Pharmacy are authorised to provide and/or administer this medication under this Patient Group Direction and agree to provide and/or administer this medication in accordance with this Patient Group Direction

Name of Health Professional	Job Title	Signed	Date