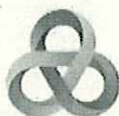




Patient Group Direction (PGD) for supply of	VARENICLINE (Champix®) FOR SMOKING CESSATION
To	CLIENTS AGED 18 YEARS AND OVER

1. Validity and Staff Characteristics	
1.1 Validity and review	<ul style="list-style-type: none">a) 15th November 2019 to 15th November 2022b) PGD number is MLCSUPGD. 070/2019 (supersedes PGD 062/2017)c) This PGD will be reviewed three months before the expiry date or sooner in the light of new guidance.d) THIS PGD SHOULD BE USED WITH THE <u>CURRENT</u> SUMMARY OF PRODUCT CHARACTERISTICS (SPC) and BRITISH NATIONAL FORMULARY (BNF).
1.2 Class and characteristics of healthcare professionals who may work with this PGD	<p>This PGD will only apply whilst the pharmacist is employed or contracted/working at the time in an accredited pharmacy within the Birmingham City Council area who:</p> <ul style="list-style-type: none">a) Is currently registered to practice on the General Pharmaceutical Council's (GPhC) register.b) Has undertaken appropriate training for working under PGDs for the supply and administration of medicines.c) Has been trained in the provision of Stop Smoking Services to the recognised National Centre for Smoking Cessation Training (NCSCT) practitioner training and registered as a provider of Birmingham City Council's Smoking Cessation service.d) Is dispensing or advising varenicline as a treatment method must firstly complete varenicline PGD training.e) Has undertaken appropriate training to carry out a clinical assessment of clients (patients) leading to conclusion that requires treatment according to the indications listed in this PGD.f) Undertakes continuing professional development (CPD).g) Should be aware of any change to the recommendations for the medicine listed. It is the responsibility of the pharmacist to keep up-to-date with continuing professional development and to work within the limitations of individual scope of practice.h) YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT. <p>Note: Please ensure that you are using the current and appropriate PGD.</p>



Patient Group Direction (PGD) for supply of	VARENICLINE (Champix®) FOR SMOKING CESSATION
To	CLIENTS AGED 18 YEARS AND OVER

2. Clinical Condition or Situation	
2.1 Clinical situation	To supply varenicline as a component of a smoking cessation support programme to smokers who have expressed a desire to quit smoking and for whom varenicline has been assessed as a suitable treatment option.
2.2 Inclusion criteria	<ul style="list-style-type: none"> a) Client agrees to receive advice and treatment from the pharmacist in line with this PGD. b) Client aged 18 years and over who resides, works or is registered with a General Practitioner (GP) practice in Birmingham. c) Dependent tobacco users identified as being sufficiently motivated to stop smoking 7-14 days after starting varenicline. d) Client is willing to continue a course of treatment which includes behavioural support for 12 weeks at agreed intervals. e) A medical history is taken and documented to establish that there are no contraindications for treatment with varenicline and that any cautions for use are recorded.
2.3 Exclusion criteria	<ul style="list-style-type: none"> a) No valid consent b) Third party request c) Client is not registered with a GP d) No consent to share information with GP e) Client under 18 years of age f) Hypersensitivity to varenicline or any of the excipients of Champix® as listed in current SPC g) Tobacco users who are not sufficiently motivated to quit h) Client is currently using other smoking cessation therapies i) Smokers already receiving varenicline prescribed by their GP j) Pregnant client or possibility of/planning pregnancy k) Breastfeeding client l) Moderate to severe renal impairment (CrCl <50ml/min) m) End-stage renal disease n) If the client has renal disease but the severity cannot be established o) Clients with active or history of psychiatric illness should be referred to their GP. p) Client receiving smoking cessation support from another provider q) Clients who have previously had Stevens-Johnson Syndrome or Erythema Multiforme s) Patients with epilepsy, a history of seizures, or conditions where the seizure threshold may be lowered t) Clients with active unstable cardiovascular disease or who have had a recent cardiovascular event in the past 3 months. u) Patients taking theophylline or aminophylline (when the client stops smoking, metabolism of theophylline and aminophylline are reduced which could cause plasma theophylline levels to rise, possibly to toxic levels if the dose of theophylline/aminophylline is not adjusted). v) Patients taking erlotinib, riociguat, methadone, clozapine, olanzapine or chlorpromazine should advise their treating physician of their intention to stop smoking prior to quitting. These patients should not be treated under this PGD.



Patient Group Direction (PGD) for supply of	VARENICLINE (Champix®) FOR SMOKING CESSATION
To	CLIENTS AGED 18 YEARS AND OVER

2.4 Action if excluded or client declines	<ul style="list-style-type: none">a) Recommend other smoking cessation options.b) Refer client to their GP (using appendix 2) or continue with alternative smoking cessation treatment as appropriate.c) Document the reason for exclusion or why client declined, and any advice given to the client along with the action taken (e.g. referred to GP).
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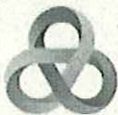
Patient Group Direction (PGD) for supply of	VARENICLINE (Champix®) FOR SMOKING CESSATION
To	CLIENTS AGED 18 YEARS AND OVER

3. Description of Treatment																
3.1 Name of medicine	Champix® (Varenicline) 0.5mg film coated tablets. Champix® (Varenicline) 1mg film coated tablets.															
3.2 Presentation of medication	0.5mg film-coated tablets: White, capsular-shaped, biconvex tablets debossed with "Pfizer" on one side and "CHX 0.5" on the other side. 1mg film-coated tablets: Light blue, capsular-shaped, biconvex tablets debossed with "Pfizer" on one side and "CHX 1.0" on the other side.															
3.3 Legal class	Prescription Only Medicine (POM)															
3.4 Dose and frequency	See section 3.5. In all circumstances (unless noted in the exclusion criteria) dosing should follow the recommendations in the varenicline Summary of Product Characteristics http://www.medicines.org.uk/emc															
3.5 Total Dose	Client should set a quit date 7 to 14 days after initiation of varenicline.															
	<table border="1"> <thead> <tr> <th>Week/Pack Type</th> <th>Details</th> <th>Dose</th> </tr> </thead> <tbody> <tr> <td>1st Supply Weeks 1 & 2 – Initiation Pack</td> <td>11 x 0.5mg & 14 x 1mg (Blister Pack)</td> <td>Days 1–3: 0.5mg once daily Days 4–7: 0.5mg twice daily Day 8-14: 1mg twice daily</td> </tr> <tr> <td>2nd Supply Weeks 3 & 4 – Maintenance Pack</td> <td>28 x 1mg (Blister Pack)</td> <td>1mg twice daily</td> </tr> <tr> <td>3rd Supply Weeks 5 to 8 – Continuation Pack</td> <td>56 x 1mg (Blister Pack)</td> <td>1mg twice daily</td> </tr> <tr> <td>4th Supply Weeks 9 to 12 – Final Pack</td> <td>56 x 1mg (Blister Pack)</td> <td>1mg twice daily</td> </tr> </tbody> </table>	Week/Pack Type	Details	Dose	1st Supply Weeks 1 & 2 – Initiation Pack	11 x 0.5mg & 14 x 1mg (Blister Pack)	Days 1–3: 0.5mg once daily Days 4–7: 0.5mg twice daily Day 8-14: 1mg twice daily	2nd Supply Weeks 3 & 4 – Maintenance Pack	28 x 1mg (Blister Pack)	1mg twice daily	3rd Supply Weeks 5 to 8 – Continuation Pack	56 x 1mg (Blister Pack)	1mg twice daily	4th Supply Weeks 9 to 12 – Final Pack	56 x 1mg (Blister Pack)	1mg twice daily
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4th Supply Weeks 9 to 12 – Final Pack	56 x 1mg (Blister Pack)	1mg twice daily														
<p>Clients who have normal renal function or mild renal impairment (CrCl between >50ml/min and ≤80ml/min) who cannot tolerate varenicline because of adverse effects (e.g. nausea) but are still motivated to continue may have their dose lowered temporarily or permanently to 0.5mg twice daily. This reduction should be agreed with the client and the stop smoking advisor. Such dose changes should not occur where the client's in possession of medication which would then be wrongly labelled. It could be considered on reviews and new issues. If there are any concerns however, encouraging GP assessment and prescription issue should be strongly considered. Where the dose is reduced to 0.5 mg twice a day, a pack of 28 x 0.5 mg tablets can be supplied for the 2nd week and 56 x 0.5mg for the 3rd and 4th supply.</p> <p>In clients with a high risk of relapse, dose tapering may be considered at the end of the standard 12 weeks of treatment (consider 0.5mg twice daily in the last two weeks of the standard 12 weeks of treatment).</p> <p>The treatment is for 12 weeks only.</p>																



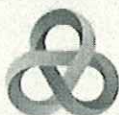
Patient Group Direction (PGD) for supply of	VARENICLINE (Champix®) FOR SMOKING CESSATION
To	CLIENTS AGED 18 YEARS AND OVER

3.6 Administration	<p>a) The pharmacist must inform the client's GP of the initial supply of varenicline within two working days by using Appendix 3.</p> <p>b) The pharmacist will complete the clinical assessment as outlined in Appendix 1 and should be held within the patient records at the Pharmacy. Including in the assessment will be the PHQ-9 assessment (Appendix 4).</p> <p>c) Clients should be asked at every appointment about their mood. If the client develops suicidal thoughts or behaviour, they should be told to stop treatment and contact their GP immediately. The pharmacist should also inform the GP.</p> <p>d) Following assessment, if the pharmacist feels that Champix® is not a suitable option as part of the client's treatment programme, they should outline the reason to the client and complete Appendix 2. This will be returned to the client's GP.</p> <p>e) If Champix® is prescribed, the pharmacist should advise the following administration:</p> <ul style="list-style-type: none">• Oral route.• Swallow tablets whole with water. Champix® can be taken with or without food.
3.7 Special Precautions	<p>a) The pharmacist will need to be monitoring the client during the smoking cessation programme.</p> <p>b) Based on insufficient clinical experience with Champix® in patients with end stage renal disease, treatment is not recommended in this patient population.</p> <p>c) Physiological changes resulting from smoking cessation, with or without treatment with Champix®, may alter the pharmacokinetics or pharmacodynamics of some medicinal products, for which dosage adjustment may be necessary (examples include theophylline, warfarin and insulin). As smoking induces CYP1A2, smoking cessation may result in an increase of plasma levels of CYP1A2 substrates. Check for drug interactions for clients on other medication.</p> <p>1) Patients on warfarin should advise the INR clinic of their intention to quit smoking using varenicline. A blood test should be arranged with the clinic as per their instructions. The pharmacist should check the patient's yellow book on every scheduled consultation ensuring that their INR is being checked regularly, and that it is within the patient's normal range. If the patient is unwilling to disclose this information, then they should be referred to their GP.</p> <p>2) Patients on insulin may be supplied with varenicline. However, they should be advised to monitor their blood glucose levels closely.</p> <p>d) Clients taking Champix® should be instructed to notify their doctor of new or worsening cardiovascular symptoms and to seek immediate medical attention if they experience signs and symptoms of myocardial infarction or stroke.</p> <p>e) According to MHRA (Medical and Healthcare products Regulatory Agency), patients should be advised to discontinue treatment and seek prompt medical advice if they develop agitation, depressed mood, or suicidal thoughts. Patients with a history of psychiatric illness should be monitored closely while taking varenicline</p>



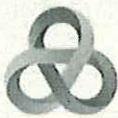
Patient Group Direction (PGD) for supply of	VARENICLINE (Champix®) FOR SMOKING CESSATION
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	<p>(note that patients with a psychiatric illness or a history of it are excluded from this PGD and must be referred to their GP).</p> <p>f) The EAGLES study (2016) has provided evidence that the use of varenicline in clients with or without a history of psychiatric disorder was not associated with a significantly increased risk of serious neuropsychiatric adverse events compared with placebo, however neuropsychiatric adverse events were reported more frequently in patients with a history of psychiatric disorders compared to those without a history of psychiatric disorders, regardless of treatment. Note that patients with a psychiatric illness or have a history it are excluded under this PGD.</p> <p>g) There have also been post-marketing reports of rare but severe cutaneous reactions, including Stevens-Johnson Syndrome and Erythema Multiforme in patients using varenicline. As these skin reactions can be life threatening, patients should discontinue treatment at the first sign of rash or skin reaction and contact a healthcare provider immediately</p> <p>h) The pharmacist should refer any patient they believe maybe renally compromised to their GP (e.g. patients on nephrotoxic drugs, diabetic patients with nephropathy, elderly patients etc).</p> <p>i) When supplying Champix® to patients with mild renal impairment the pharmacist must have seen a recent blood test result (at least within the last three months), ideally this would be the last blood test they had indicating their renal function. If the pharmacist does not have reasonable assurance as to the patient's renal function, they must refer the patient back to their GP (n.b. patient with moderate to severe renal impairment or end-stage renal failure are excluded from this PGD).</p>
3.8 Adverse Reactions	<p>a) Common or very common adverse reactions according to the BNF include: Appetite abnormal; asthenia; chest discomfort; constipation; diarrhoea; dizziness; drowsiness; dry mouth; gastrointestinal discomfort; gastrointestinal disorders; headache; joint disorders; muscle complaints; nausea; oral disorders; pain; skin reactions; sleep disorders; vomiting; weight increased</p> <p>b) Uncommon adverse reactions according to the BNF include: Allergic rhinitis; anxiety; arrhythmias; behaviour abnormal; burping; conjunctivitis; depression; eye pain; fever; fungal infection; haemorrhage; hallucination; hot flush; hyperglycaemia; influenza like illness; malaise; menorrhagia; mood swings; numbness; palpitations; seizure; sexual dysfunction; suicidal ideation; sweat changes; thinking abnormal; tinnitus; tremor urinary disorders;</p> <p>c) Rare or very rare adverse reactions according to the BNF include: Angioedema; bradyphrenia; coordination abnormal; costochondritis; cyst; diabetes mellitus; dysarthria; eye disorders; feeling cold; glycosuria; muscle tone increased; polydipsia; psychosis; scleral discolouration; severe cutaneous adverse reactions (SCARs); snoring; vaginal discharge; vision disorders</p> <p>d) This list is not exhaustive. Refer to the current BNF and SPC for a detailed list.</p>



Patient Group Direction (PGD) for supply of	VARENICLINE (Champix®) FOR SMOKING CESSATION
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	<p>e) Report suspected adverse reactions to the GP and Medical and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme (www.mhra.gov.uk/yellowcard).</p>
3.9 Advice to client	<p>a) Quit date should be 7 to 14 days after initiation of varenicline.</p> <p>b) Dose and method of administration of varenicline.</p> <p>c) Possible side effects and actions client can take to manage them.</p> <p>d) Supply client with a Patient Information Leaflet (PIL).</p> <p>e) Client to notify their doctor of new or worsening cardiovascular symptoms and to seek immediate medical attention if they experience signs and symptoms of myocardial infarction or stroke.</p> <p>f) Client should be advised to discontinue treatment and seek prompt medical advice if they develop agitation, depressed mood, or suicidal thoughts.</p> <p>g) Varenicline is not a magic cure; effort and determination are crucial. Varenicline does not remove all temptation to smoke but does make abstinence easier. It works by acting on parts of the brain which are affected by nicotine in cigarettes.</p> <p>h) Clients should exercise caution before driving or using machinery until they are reasonably certain that varenicline does not adversely affect their performance.</p> <p>i) Possible changes in the body on stopping smoking, e.g. weight gain and how to manage this.</p> <p>j) The major reasons for varenicline failure are:</p> <ol style="list-style-type: none">1) Unrealistic expectations.2) Unable to tolerate side-effect of nausea.3) Insufficient or incorrect use of medication.4) Insufficient support from a trained smoking advisor. <p>k) Client may be discharged from the smoking cessation service before the end of the 12 weeks treatment if they do not follow agreed action plan or if a change in their medical condition makes varenicline contraindicated.</p> <p>l) Expectations of both the client and pharmacist with reference to the ongoing treatment and future appointments.</p> <p>m) Next appointment with the pharmacist.</p> <p>n) It is important to make sure that the client understands the following points:</p> <ol style="list-style-type: none">1) Varenicline is an effective medication but effort and determination are also necessary.2) It works by acting on the parts of the brain which are affected by nicotine in cigarettes.3) It does not remove all temptation to smoke, but it does make abstinence easier.4) Varenicline is safe, but about a third of clients may experience mild nausea some 30 minutes after taking it. This reaction usually diminishes gradually over the first few weeks, and most clients tolerate it without problems.



Patient Group Direction (PGD) for supply of	VARENICLINE (Champix®) FOR SMOKING CESSATION
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	<p>o) Instruct on correct use and daily dose. Use mock product packaging for the explanation. Clients should take varenicline for 7 to 14 days before stopping smoking.</p> <p>p) No clinically significant drug interactions have been reported.</p>
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4. Records, Facilities and Follow-up	
4.1 Records to be kept for audit purposes	<p>a) Client's details (name, address and date of birth).</p> <p>b) The consent of the client.</p> <p>c) GP contact details.</p> <p>d) GP has been informed that client has started a course of Champix® for smoking cessation (Appendix 2).</p> <p>e) Date of attendance and clinical indication.</p> <p>f) Past and present medical history.</p> <p>g) Drug history and any known allergy.</p> <p>h) Motivation to quit status.</p> <p>i) Record that Champix® was dispensed under a PGD.</p> <p>j) Record the doses dispensed on the computerised PMR (patient medication record).</p> <p>k) Batch numbers and expiry dates of Champix® dispensed. (Appendix 5).</p> <p>l) The pharmacist issuing Champix® should complete a PHQ-9 health questionnaire with all patients (Appendix 4).</p> <p>m) Details of any adverse reactions and what action taken.</p> <p>n) Any follow-up/ referral arrangement.</p> <p>o) Name and signature of pharmacist who dispensed the medication.</p> <p>p) Any other relevant information according to the service specification to ensure compliance with the Primary Care Contract.</p>
4.2 Location facilities and supplies which must be available	<p>a) The consultation will be carried out in a consultation room.</p> <p>b) Store in the original pack below 30°C.</p>
4.3 Follow up treatment	<p>a) Pharmacist should offer weekly support for at least the first four weeks following the quit date. Appointments should be scheduled when clients are booked into treatment.</p> <p>b) Support up to 12 weeks should be offered based on client's need.</p>



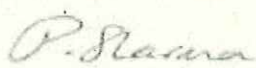

Patient Group Direction (PGD) for supply of	VARENICLINE (Champix®) FOR SMOKING CESSATION
To	CLIENTS AGED 18 YEARS AND OVER


5. Key References	
5.1	Online BNF, Varenicline, Champix®, October 2019: https://bnf.nice.org.uk/drug/varenicline.html (accessed October 2019).
5.2	Pfizer Limited, Champix®, Summary of Product Characteristics (SPC), October 2019: https://www.medicines.org.uk/emc/product/266/smpc (accessed October 2019).
5.3	NICE TA123, Varenicline for smoking cessation, July 2007: http://www.nice.org.uk/TA123 July 2007 (accessed October 2019).
5.4	NICE Public health guidance, PH45 - Tobacco: harm-reduction approaches to smoking, June 2013 (updated July 2013): http://www.nice.org.uk/guidance/ph45 (accessed October 2019).
5.5	NICE Clinical Knowledge Summary, Smoking Cessation, March 2018: https://cks.nice.org.uk/smoking-cessation (accessed October 2019).
5.6	NICE MPG Patient Group Directions, Aug 2013 (updated March 2017): https://www.nice.org.uk/guidance/mpg2 (accessed July 2017).
5.7	Specialist Pharmacy Service, UKMI Medicines Q&As, What are the clinically significant drug interactions with cigarette smoking? (November 2017): https://www.sps.nhs.uk/wp-content/uploads/2017/11/UKMI_QA_Drug-interactions-with-smoking-cigarettes_update_Nov-2017.pdf (accessed October 2019).

6. Managerial Content	
6.1	a) This PGD must be agreed to and signed by all pharmacists using it. b) If this PGD is updated or replaced; ensure that all older versions are withdrawn from use with immediate effect. c) This PGD must be easily accessible in the clinical setting as a working document.
6.2	<u>For Comments about this PGD:</u> Please direct comments specifically relating to the information on this PGD to: Medicines Management Team Midlands and Lancashire CSU T: 0121 612 4109 E: mlcsu.medicines-management@nhs.net



Patient Group Direction (PGD) for supply of	VARENICLINE (Champix®) FOR SMOKING CESSATION
To	CLIENTS AGED 18 YEARS AND OVER

7. This PGD was developed and reviewed by:			
Post	Name	Signature	Date
7.1 Lead Pharmacist	Pooja Sharma		13.11.2019
7.2 Lead Doctor	Dr Paul Dudley		13.11.2019
This PGD was peer reviewed by:			
Kuldip Soora Senior Prescribing Advisor Midlands and Lancashire CSU	Bhavna Taank Public Health Primary Care Service Lead. Population Health, Wellbeing and Care. Birmingham City Council	Kathy Lee Senior Officer – Public Health Nurse Population Health & Care Birmingham Public Health	Karl Beese Commissioning Manager Adult Public Health Services Birmingham City Council

8. This PGD has been Authorised for use in Birmingham (Council) Public Health by:			
Post	Name	Signature	Date
Director of Public Health	Justin Varney		19/11/2019



Patient Group Direction (PGD) for supply of	VARENICLINE (Champix®) FOR SMOKING CESSATION
To	CLIENTS AGED 18 YEARS AND OVER

9. This PGD has been authorised for use from the following premises:	
9.1 Name of premises	
9.2 Address or Contact details	
9.3 Name of Manager	
9.4 Signature	
9.5 Date	

10. Individual Authorisation	
10.1	It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own code of professional conduct.
10.2	It is your responsibility to make sure you are using the current version of this PGD.
10.3	I have read and understood this PGD and agree to administer this medicine only in accordance with this PGD.
10.4	PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY.

Note to Authorising Managers: Authorised staff should be provided with an individual copy of the clinical content of this PGD and a photocopy of the authorisation sheet showing their authorisation.

Name of Professional	Signature	Authorising Manager	Date

Pharmacist's Clinical Assessment to Supply Varenicline (Champix®)

Client Name _____ DOB _____

Client Address _____

Name of referring Birmingham City Council contracted Stop Smoking Service Provider
_____**Is the client sufficiently motivated to stop smoking?**

If no, DO NOT continue with this form or supply varenicline - advise the client to return when they are ready to make a quit attempt.

Criteria for Exclusion

	Yes	No
Is the client sensitive to varenicline tartrate or any of its excipients?		
Is the client using other smoking cessation therapies?		
Is the client under 18 years old?		
Does the client have moderate to severe or end-stage renal disease?		
Is the client pregnant or planning a pregnancy?		
Is the client breastfeeding?		
Does the client have epilepsy or a condition that lowers the seizure threshold?		
Does the client have a history of serious psychiatric illness?		
Does the client have active unstable cardiovascular disease, or have they had a cardiovascular event in the last 3 months?		
Has the client previously had Stevens-Johnson Syndrome or Erythema Multiforme?		

If the client answers yes to any of the above then varenicline may not be suitable. Other options available to the client are:

- Contact the specialist stop smoking service for advice
- offer the option of NRT
- refer client to their GP using the Notification Form in **Appendix 2**

If in doubt seek further advice from the client's GP

Name of Pharmacist:**Date:****Signature:**

Pharmacist referral to GP: patients excluded from varenicline PGD

URGENT & CONFIDENTIAL FAX

Data protection confidentiality note: this message is intended only for the use of the individual or entity to whom it is addressed and may contain information that is privileged, confidential and exempt from disclosure under law. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited.

Pharmacy Stamp

FAO: GP Name _____

GP Address _____

Notification of consultation and non-supply of varenicline

Client's Name _____

Address _____

DOB _____

Telephone _____

Dear Doctor

A consultation has taken place with your patient in accordance with the Birmingham City Council's varenicline Patient Group Direction to assess whether it is appropriate for them to receive varenicline. However, no supply under the PGD has been made, due to the following being identified:

(Summarise here details from assessment form (Appendix 1))

CONSENT

I, _____ (client name) confirm that the above information has been discussed with me and is an accurate record of that discussion.

I give my consent to the above information to be passed to my GP.

Signature: _____ Date: _____

Name of Pharmacist: _____

Date: _____

Signature: _____

Pharmacist Notification to GP of supply of varenicline

URGENT & CONFIDENTIAL FAX

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Pharmacy Stamp

FAO: GP Name _____

GP Address _____

Notification of supply of varenicline

Client's Name _____

Address _____

DOB _____

Telephone _____

Dear Doctor

I write to advise you that your patient has been seen by me for smoking cessation treatment. They have expressed a wish to use varenicline to aid their effort in stopping smoking, and a medical history has taken place to assess whether it is appropriate for them to receive it. I have ascertained that your patient does not have any contraindications, or risk factors, for taking varenicline and meets the criteria for a supply to be made under the local Patient Group Direction. If you have any concerns about this person commencing varenicline then please do not hesitate to contact me.

Name: _____ Phone No: _____

Signature: _____ Date: _____

Client is receiving varenicline from this pharmacy:

Name of Pharmacy: _____

Address: _____

PATIENT HEALTH QUESTIONNAIRE (PHQ-9)

NAME: _____ DATE: _____

Over the last 2 weeks, how often have you been bothered by any of the following problems?
(use "✓" to indicate your answer)

	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself – or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so figety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead, or of hurting yourself	0	1	2	3

add columns + +

(Healthcare professional: For interpretation of TOTAL, TOTAL: please refer to accompanying scoring card).

10. If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	Not difficult at all	_____
	Somewhat difficult	_____
	Very difficult	_____
	Extremely difficult	_____

PHQ-9 Patient Depression Questionnaire

For initial diagnosis:

1. Patient completes PHQ-9 Quick Depression Assessment.
2. If there are at least 4 ✓s in the shaded section (including Questions #1 and #2), consider a depressive disorder. Add score to determine severity.

Consider Major Depressive Disorder

- if there are at least 5 ✓s in the shaded section (one of which corresponds to Question #1 or #2)

Consider Other Depressive Disorder

- if there are 2-4 ✓s in the shaded section (one of which corresponds to Question #1 or #2)

Note: Since the questionnaire relies on patient self-report, all responses should be verified by the clinician, and a definitive diagnosis is made on clinical grounds taking into account how well the patient understood the questionnaire, as well as other relevant information from the patient.

Diagnoses of Major Depressive Disorder or Other Depressive Disorder also require impairment of social, occupational, or other important areas of functioning (Question #10) and ruling out normal bereavement, a history of a Manic Episode (Bipolar Disorder), and a physical disorder, medication, or other drug as the biological cause of the depressive symptoms.

To monitor severity over time for newly diagnosed patients or patients in current treatment for depression:

1. Patients may complete questionnaires at baseline and at regular intervals (eg, every 2 weeks) at home and bring them in at their next appointment for scoring or they may complete the questionnaire during each scheduled appointment.
2. Add up ✓s by column. For every ✓: Several days = 1 More than half the days = 2 Nearly every day = 3
3. Add together column scores to get a TOTAL score.
4. Refer to the accompanying PHQ-9 Scoring Box to interpret the TOTAL score.
5. Results may be included in patient files to assist you in setting up a treatment goal, determining degree of response, as well as guiding treatment intervention.

Scoring: add up all checked boxes on PHQ-9

For every ✓ Not at all = 0; Several days = 1;
More than half the days = 2; Nearly every day = 3

Interpretation of Total Score

Total Score	Depression Severity
1-4	Minimal depression
5-9	Mild depression
10-14	Moderate depression
15-19	Moderately severe depression
20-27	Severe depression

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Pharmacist's Varenicline Supply Record (to be retained by Pharmacist for audit purposes)

Name _____ Date of Birth _____

Date	Supplied	Batch number	Expiry date	Confirm client seen by Stop Smoking Adviser for behavioural support since last supply – insert date or ✓	Notes e.g. advice given, adverse effects
	Starter pack				
	Follow on pack				

