

This Patient Group Direction (PGD) must only be used by community pharmacists who have been named and authorised by their organisation to practice under it. The PGD must only be used in conjunction with a local authority commissioned stop smoking service specification. The most recent and in date final signed version of the PGD should be used.

# Patient Group Direction

for the supply of

## Varenicline tablets

by Community Pharmacists in Cheshire and Merseyside  
- as part of a stop smoking service -

Version number: 6.4

**Effective from:      October 26<sup>th</sup> 2020**

**Expires:              October 25<sup>th</sup> 2023**




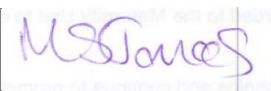
## Change history

Version number	Change details	Date
1.0	Original version developed by Edwards, Gallard, Stubbs, Murphy, Mills, Gardiner & Major	December 2014
2.0	Completely reviewed and updated (Dec 16 – Jan 17)	January 2017
3.0	Final version circulated to development group for comments	February 2017
4.0	Version 3 amended according to comments from Helen Murphy of CPCW.	March 2017
5.0	Amended following comments from LPC in Liverpool	6 <sup>th</sup> April 2017
6.0	1 <sup>st</sup> draft completed and circulated to the development group for comments	10 <sup>th</sup> June 2020
6.1	2 <sup>nd</sup> draft circulated to the development group for comments (following Development Group meeting in July)	5 <sup>th</sup> August 2020
6.2	Final draft circulated to the development group (following Development Group meeting in August)	22 <sup>nd</sup> September 2020
6.3	Final PGD approved following no further comments	29 <sup>th</sup> September 2020
6.4	Comment received regarding records to be kept (page 12). PGD amended prior to going live.	13 <sup>th</sup> October 2020

## PGD Approval / development

	Name	Job title and organisation
Members of the PGD approval/development group	Pooja Sharma	Senior Prescribing Advisor, MLCSU
	Kuldip Soora	Senior Prescribing Advisor, MLCSU
	Adit Jain	GP Advisor, Knowsley CCG
	Clair Harris	Interim Commissioning Manager, Knowsley Metropolitan Borough Council
	Louise Gatley	Joint Chief Officer, Halton, St Helens & Knowsley Local Pharmaceutical Committee
	Helen Murphy	Joint Chief Officer, Halton, St Helens & Knowsley Local Pharmaceutical Committee
	Elizabeth Woodworth	Head of Smoking Cessation Service, Wirral
	Jessica Smith	Population Health Officer, Sefton Borough Council
	Adam Major	Medicines Management Project Support, Champs Public Health Collaborative
	Hannah Sharp	Project officer, Champs Public Health Collaborative

## PGD authorisation

	Name	Job title and organisation	Signature	Date
Senior Pharmacist & Lead Author	Pooja Sharma GPhC No. 2080022	Senior Prescribing Advisor (PGD Lead), MLCSU		13.10.2020
Lead Doctor	Dr Adit Jain GMC No. 6027646	GP Advisor, Knowsley CCG		16.10.2020
Representative of profession using PGD	Louise Gatley GPhC No: 2042202	Joint Chief Officer, Halton, St Helens & Knowsley Local Pharmaceutical Committee		16.10.2020
Person signing on behalf of authorising body / Commissioning Organisation	Margaret Jones	Director of Public Health, Sefton Council		05/11/2020

## Community Pharmacist agreement to practise under the varenicline 0.5mg and 1mg tablets Patient Group Direction (PGD) for Community Pharmacists

### Practitioner

I have read the [Insert Commissioner Name] Patient Group Direction (PGD) for the [Insert Service Name] service and agree to follow them in accordance with the criteria described in the PGD and Service Specification.

Name	GPhC Number	Signature	Date

### Authorising Manager

I confirm that the pharmacists named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of [insert name of organisation] for the above-named pharmacists who have signed the PGD to work under it.

Name	Designation	Signature	Date

### Note to authorising manager

Score through unused rows in the list of practitioners to prevent pharmacist additions post managerial authorisation.

A copy of this PGD with completed practitioner authorisation sheet should be retained and available at the pharmacy premises as a record of those pharmacists authorised to work under this PGD.

## Training and competency of registered Community Pharmacists

	Requirements of registered Community Pharmacists working under the PGD
Qualifications and professional registration	Community Pharmacists currently registered with the General Pharmaceutical Council (GPhC), who are working in a pharmacy contracted to NHS England North (Cheshire and Merseyside).
Competency	The pharmacist must satisfy the requirements of the self-declaration of Competence (DOC) according to the “Centre for Pharmacy Postgraduate Education (CPPE) programme for smoking cessation intervention service – stop smoking advice: Pharmacist supply of prescription only medicines via a PGD.”
	Has undertaken appropriate training for working under PGDs for the supply and administration of medicines.
	Undertakes continuing professional development (CPD).
	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 CPD and to work within the limitations of individual scope of practice.

**YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT.**

**Note: Please ensure that you are using the current and appropriate PGD.**

## Clinical condition

<b>Clinical condition or situation to which this PGD applies</b>	<p>Aid to facilitate smoking cessation in patients receiving specialist advice and support from local stop smoking services in Cheshire and Merseyside who have expressed a desire to quit smoking and for whom varenicline has been assessed as a suitable treatment option.</p>
<b>Inclusion criteria</b>	<ul style="list-style-type: none"> <li>• Smokers aged 18 years or older</li> <li>• Dependent tobacco users identified as being sufficiently motivated to stop smoking 7-14 days after starting varenicline</li> <li>• Patient is willing to continue a course of treatment which includes behavioural support for 12 weeks at agreed intervals from their referring stop smoking service</li> <li>• Patient must consent to sharing information with their GP via local system</li> <li>• Patient agrees to receive advice and treatment from the pharmacist in line with this PGD</li> <li>• The patient's medical history has been checked against the inclusion and exclusion criteria and they are deemed to be eligible to be treated under this PGD (refer to appendix 1 and 2)</li> </ul>
<b>Exclusion criteria</b>	<ul style="list-style-type: none"> <li>• Under the age of 18 years</li> <li>• No valid consent</li> <li>• Hypersensitivity to varenicline or any of its excipients</li> <li>• Previous side effects with varenicline use that was not managed by reducing the dose</li> <li>• Third party supply</li> <li>• Patient is not registered with a GP</li> <li>• Patient is receiving varenicline support from another provider</li> <li>• No consent to share information with their GP</li> <li>• Patient continues to smoke after 14 days of initiating varenicline or has no intention to quit smoking</li> <li>• Varenicline being used to support harm reduction in smokers who do not feel able to quit</li> <li>• Tobacco users who are not sufficiently motivated to quit</li> <li>• Concurrent use of another stop smoking aid (e.g. nicotine patch or e-cigarette)</li> <li>• Patients drinking more than 14 units of alcohol per week</li> <li>• Pregnant or possibility of/planning pregnancy</li> <li>• Breast feeding</li> <li>• Patients who are currently referred to or are under</li> </ul>

	<p>investigation by a psychiatrist or mental health team.</p> <ul style="list-style-type: none"> <li>• Patients who are taking regular antipsychotic medication (e.g. clozapine, olanzapine, haloperidol or chlorpromazine)</li> <li>• Patients who have a history of a severe mental health disorder e.g. schizophrenia, psychosis, bipolar or suicidal thoughts/attempts.</li> <li>• Patients who are currently being treated for severe depression (e.g. are being seen or supported by a specialist mental health team)</li> <li>• Patients with a mental health condition who are not yet stabilised in their treatment</li> <li>• Short term episodes such as a reaction to a bereavement (not requiring treatment) are <u>not</u> excluded under this PGD.</li> <li>• Patients who have already had 2 previous attempts at quitting smoking with varenicline within the last 12 months (patient to self-report previous use).</li> <li>• History of seizures/convulsions, taking anti-epileptic medications or with other conditions that potentially lower the seizure threshold.</li> <li>• Known renal impairment or undergoing investigations for renal impairment</li> <li>• The pharmacist should refer any patient they believe may be renally compromised to their GP (e.g. patients on nephrotoxic drugs, diabetic patients with nephropathy, elderly patients etc).</li> <li>• History of Stevens-Johnson Syndrome or Erythema Multiforme.</li> <li>• Patients taking erlotinib, riociguat, methadone, clozapine, olanzapine, chlorpromazine or flecainide should advise their treating physician of their intention to stop smoking prior to quitting. These patients should not be treated under this PGD.</li> <li>• Patients with active unstable cardiovascular disease or who have had a recent cardiovascular event in the past 3 months</li> <li>• If the pharmacist has any doubts about diabetic patient's monitoring their blood glucose levels (these patients should be referred to their GP).</li> </ul> <p><b>N.B.</b> Any patient who is excluded should be signposted back to the referring service, a pharmacy Stop Smoking Service for NRT if appropriate and available, or to their GP.</p>
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<p><b>Cautions (including any relevant action to be taken)</b></p>	<ol style="list-style-type: none"> <li>1) Smoking cessation (with or without pharmacotherapy) has been associated with the exacerbation of underlying psychiatric illness (e.g. depression). Changes in behaviour or thinking, anxiety, psychosis, mood swings, aggressive behaviour, depression, suicidal ideation and behaviour and suicide attempts have been reported in patients attempting to quit smoking. Patients should be advised to discontinue varenicline immediately and notify their doctor and pharmacist if they experience serious neuropsychiatric symptoms such as agitation, depressed mood, changes in behaviour or thinking, or develop suicidal ideation or suicidal behaviour.</li> <li>2) Patients with mild to moderate mental health disorders including mild to moderate depression or anxiety should be advised to discontinue varenicline immediately and notify their doctor and pharmacist if they experience worsening symptoms.</li> <li>3) Patients taking varenicline 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.</li> <li>4) Patients reporting hypersensitivity reactions (including angioedema) and/or severe skin reactions (e.g. Stevens Johnson syndrome) should discontinue treatment and contact a healthcare provider immediately. Although rare, these reactions have been identified from post-marketing reports.</li> </ol> <p><b>General warning about problems which could affect any patients who stop smoking (irrespective of stop smoking medication)</b></p> <p>Physiological changes resulting from smoking cessation, with or without treatment with varenicline, may alter the pharmacokinetics or pharmacodynamics of some medicinal products, for which dosage adjustment may be necessary (examples include theophylline, warfarin, methadone, and insulin). As smoking induces CYP1A2, smoking cessation may result in an increase of plasma levels of CYP1A2 substrates. Certain antipsychotic medications are also affected by this warning, but patients on these medicines are excluded from this PGD. Check for drug interactions for patients on other medication.</p> <ol style="list-style-type: none"> <li>1) The pharmacist will need to review the patient during the smoking cessation programme.</li> <li>2) Patients should be reviewed at each collection point to ensure that any relevant monitoring has been carried out</li> </ol>
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	<p>by their health care professional.</p> <p>3) 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>4) Patients on insulin may be supplied with varenicline. However, they should be advised to monitor their blood glucose levels closely. If the pharmacist has any doubts around the patient monitoring their blood glucose levels should be referred to their GP.</p> <p>5) Patients taking theophylline or aminophylline (when the patient 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). The pharmacist must inform the patient's GP of their intention to quit and agree subsequent additional monitoring by the GP before the patient's quit date. They must also liaise with the GP throughout the patient's treatment as appropriate to ensure levels are being monitored and reviewed.</p>
<b>Arrangements for referral for medical advice</b>	Refer to GP.
<b>Action to be taken if patient excluded</b>	<ul style="list-style-type: none"> <li>• Refer back to the service which made the assessment for the patient to be offered alternative therapy. See notes under "Cautions" and "Exclusion criteria".</li> <li>• Recommend alternative smoking cessation treatments if appropriate</li> <li>• Refer to GP</li> <li>• Document the reason for exclusion and any advice given to the patient along with the action taken (e.g. referred to GP)</li> </ul>
<b>Action to be taken if patient declines treatment</b>	<ul style="list-style-type: none"> <li>• Refer to smoking cessation service</li> <li>• Document the reason for why the patient declined and any advice given to the patient along with the action taken (e.g. referred to smoking cessation service).</li> </ul>

## Details of the medicine

<b>Name, form and strength of medicine</b>	Varenicline (as tartrate) 0.5mg and 1mg tablets (Champix®)
<b>Legal category</b>	Prescription Only Medicine (POM)
<b>Indicate any off-label use</b>	Not applicable
<b>Route/method of administration</b>	Orally, swallowed whole with water and taken either with or without food.
<b>Dose and frequency</b>	<p><b>Initiation pack</b> (<i>weeks 1 and 2</i>)  <b>(days 1 to 3):</b> 0.5mg once daily  <b>(days 4 to 7):</b> 0.5mg twice daily  <b>(days 8 to 14):</b> 1mg twice daily  Patients should start this treatment 1 to 2 weeks before their specified quit date.</p> <p><b>Maintenance packs</b> (<i>weeks 3 to 12</i>)  <b>(day 15 onwards):</b> 1mg twice daily until a total of 12 weeks' treatment has been taken. (Reduce dose to 0.5mg twice daily if not tolerated – see below).</p> <p>Patients 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 patient and the stop smoking advisor. Dose reductions should be initiated at review points for repeat supply. If there are any concerns however, encouraging GP assessment and prescription issue should be strongly considered.</p> <p>In patients with a high risk of relapse, if the patient is experiencing side effects for example irritability because of initial discontinuation, please refer to GP for consideration of further/tapering doses.</p>
<b>Quantity to be administered and/or supplied</b>	<ul style="list-style-type: none"> <li>• Patients should be supplied an initiation pack containing 11 x 0.5mg(white) tablets and 14 x 1mg(blue) tablets</li> <li>• Five maintenance packs each containing 28 x 1mg tablets should be supplied in instalments to give a total of 12 weeks' therapy. If the patient's dose is reduced to 0.5mg twice daily, then 28 x 0.5mg tablets can be supplied in instalments as specified above.</li> <li>• GP to be notified within 2 days of first supply via usual communication channels.</li> </ul>
<b>Maximum or minimum treatment period</b>	Patients should be treated with varenicline for a maximum of 12 weeks. The product license permits an additional 12-week course, but this is not permitted under this PGD.
<b>Adverse effects</b>	<ul style="list-style-type: none"> <li>• 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</li> <li>• Uncommon adverse reactions according to the BNF include:</li> </ul>

	<p>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> <ul style="list-style-type: none"><li>• 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</li><li>• Frequency not known of adverse reactions according to the BNF: Loss of consciousness</li></ul> <p><b>This list is not exhaustive, see the current SPC and BNF for full list of adverse effects.</b></p> <p>All serious adverse drug reactions should be reported using the yellow card system <a href="http://www.mhra.gov.uk/yellowcard">www.mhra.gov.uk/yellowcard</a>.</p> <p>All practitioners and managers have a duty to report any patient safety incidents or concerns related to the operation of this PGD through their organisation's incident reporting system (see local service level agreement).</p>
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<p><b>Records to be kept</b></p>	<p>A consultation proforma for the “Supply of varenicline” must be fully completed and signed* for all consultations, irrespective of whether a supply is made. Appropriate records will be kept which will be agreed locally and must include the following:</p> <ul style="list-style-type: none"> <li>○ That valid informed consent has been given</li> <li>○ Patient’s name, address and date of birth</li> <li>○ Name of GP</li> <li>○ Specify how the patient has/has not met the criteria of the PGD</li> <li>○ Dose given</li> <li>○ Date and time of supply</li> <li>○ Relevant past and present medical history</li> <li>○ Documentation of cautions as appropriate</li> <li>○ Advice given if patient excluded or declines treatment</li> <li>○ Details of any ADRs/allergy status and actions taken</li> <li>○ Signature*, GPhC number and name of pharmacist who supplied the medication</li> <li>○ The supply must be entered in the Patient Medication Record (PMR)</li> <li>○ Batch numbers and expiry dates of varenicline dispensed</li> <li>○ All records should be clear, legible and contemporaneous.</li> <li>○ Patient safety incidents, such as medication errors, near misses and suspected adverse events</li> <li>○ Any additional requirements in accordance with the local authority service specification</li> </ul> <p>This can be a paper or electronic version (or both) and includes paper documentation (such as referral letters) if these have not been electronically scanned. In accordance with national guidance, all records should be kept for 8 years. This includes patient data, master copies of the PGD and lists of authorised practitioners.</p> <p>*A signature is required if paper records are kept. If documented electronically and an electronic signature cannot be recorded, there must be an auditable trail of the Pharmacist’s activity.</p>
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## Patient information

<p><b>Written information and advice to be given to patient or carer</b></p>	<ul style="list-style-type: none"> <li>● Patient Information Leaflet supplied with the pack plus any additional information in accordance with the local service specification.</li> <li>● Patient should be warned that the medicine may make them sleepy and not to drive or operate machinery/tools if affected.</li> </ul>
<p><b>Follow-up advice to be given to patient or carer</b></p>	<ul style="list-style-type: none"> <li>● <b>Users should be advised to discontinue treatment and seek prompt medical advice if they develop agitation, depressed mood, or suicidal thoughts (MHRA/CHM advice) and also to contact the pharmacist or the Stop Smoking service.</b></li> <li>● Actions to be taken by patients with a history of mild to</li> </ul>

	<p>moderate mental health disorders and if their symptoms worsen i.e discontinue treatment and report to the GP and pharmacist as soon as possible.</p> <ul style="list-style-type: none"> <li>• Diabetic patients should be told to be extra vigilant for signs of hypoglycaemia and to monitor blood glucose more frequently (patients not confident to monitor their blood glucose levels should be referred to their GP).</li> <li>• Patients on warfarin need to advise their INR clinic of their intention to quit smoking using varenicline. They should bring their yellow book with them to review meetings</li> <li>• Patients on theophylline/aminophylline will need to have their levels monitored by their GP</li> <li>• Patients should be advised to set a quit date 7 to 14 days after initiation.</li> <li>• Dose and method of administration including how to use the initiation pack.</li> <li>• The major reasons for varenicline failure are: <ul style="list-style-type: none"> <li>- Unrealistic expectations;</li> <li>- Lack of preparation for the potential for the tablets to cause nausea;</li> <li>- Insufficient or incorrect use;</li> <li>- Insufficient support from a trained smoking advisor.</li> </ul> </li> <li>• It is important to make sure that the patient understands the following points: <ul style="list-style-type: none"> <li>- It works by acting on the parts of the brain which are affected by nicotine in cigarettes;</li> <li>- It does not remove all temptation to smoke, but it does make abstinence easier;</li> <li>- Approximately one third of patients may experience mild nausea around 30 minutes after taking varenicline. This reaction usually diminishes gradually over the first few weeks, and most people tolerate it without problems. If severe, patients should be referred to their G.P.</li> <li>- Smoking cessation with or without treatment is associated with various symptoms. Patients should be made aware that they may experience any of these side effects but it is not clear whether the effects are linked to therapy or to nicotine withdrawal.</li> </ul> </li> <li>• Possible side effects and actions patient can take to manage them.</li> <li>• At the end of treatment, discontinuation of varenicline has been associated with an increase in irritability, urge to smoke, depression, and/or insomnia in up to 3% of users.</li> <li>• Patient 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.</li> </ul>
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	<ul style="list-style-type: none"><li>• Patient should exercise caution before driving or using machinery until they are reasonably certain that varenicline does not adversely affect their performance. Occupational risk should be highlighted to patients as appropriate.</li><li>• Possible physical changes on stopping smoking, e.g. weight gain and how to manage this</li><li>• Patient may be discharged from the 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.</li><li>• Expectations of both the patient and pharmacist with reference to the ongoing treatment and future appointments.</li><li>• Next contact with the pharmacist.</li><li>• If treatment is needed beyond the 12-week period covered by this PGD the patient will need to be referred back to their GP.</li></ul>
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Managerial content

This PGD must be agreed to and signed by all pharmacists using it.

If this PGD is updated or replaced; ensure that all older versions are withdrawn from use with immediate effect.

**This PGD must be easily accessible in the clinical setting as a working document.**

Comments about this PGD

Please direct comments specifically relating to the information in this PGD to the Midlands and Lancashire CSU Medicines Management Team via the following e-mail:  
mlcsu.medicines-management@nhs.net

## Key references

Electronic Medicines Compendium. CHAMPIX 0.5 mg film-coated tablets - Summary of Product Characteristics (SmPC). [online] Available at:

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UK Medicines Information (UKMI) (2020). What are the clinically significant drug interactions with cigarette smoking?.

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Medicines and Healthcare products Regulatory Agency (2009). Smoking and smoking cessation: clinically significant interactions with commonly used medicines. [online] GOV.UK.

Available at: <https://www.gov.uk/drug-safety-update/smoking-and-smoking-cessation-clinically-significant-interactions-with-commonly-used-medicines> [accessed on 15<sup>th</sup> May 2020].

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Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6055735/> [Accessed 21<sup>st</sup> September 2020].



## **Appendix 1**

### Patient Assessment Form Guidance for Stop Smoking Advisors – How to complete and why?

For patients who prefer varenicline for their smoking cessation therapy, the following form (appendix 2) should be completed.

#### **Social history**

It is important to consider a person's social history. Often a person will not realise that their level of alcohol consumption is excessive, and they should be encouraged to be honest about their level of drinking. Those patients that drink excessively (>14 units of alcohol per week) may benefit from referral to other services for support to reduce their drinking in the first instance. Alternatively consider the use of NRT for these patients.

#### **Screening questions – Medical history**

Patients that have depression, anxiety or other mental health disorders (including eating disorders) should be informed that stopping smoking may increase their risk of impulsive self-harm or suicide regardless of treatment option used. Patients that have stable mild-moderate mental health disorders are still eligible for treatment with varenicline under this PGD, however, if receiving treatment (pharmacological or counselling/listening services) for their mental health disorder they should be advised to let the person responsible for their care know that they are stopping smoking.

Patients with a history of severe mental health disorders such as schizophrenia, bipolar disorder or psychosis should be advised that the evidence for the use of varenicline is not sufficiently clear to allow its use in this patient group.

Patients with renal impairment or unstable cardiovascular disease should be referred to their GP for further assessment (where available) or they can be offered treatment with NRT.

Patients that have been diagnosed with a seizure disorder should be referred to their GP for further assessment or they can be offered treatment with NRT.

#### **General**

Although patients can decide which option they prefer, it should be stressed that the pharmacist may still not be able to supply varenicline under the PGD due to their medical conditions(s) or medication.

## Appendix 2

### Patient Assessment Form for Varenicline

As you have chosen to consider varenicline as your medication to help you stop smoking, please complete the questions below. As it has already been discussed with you, this treatment has side effects. These medicines are not appropriate for everyone if you have certain medical conditions or other medicines that may interfere with these treatments. If you do not answer a question or want to speak to a smoking advisor/pharmacist confidentially, please highlight this to them.

If you are commenced on varenicline a letter will be sent to your GP to inform them, you must consent to this to receive treatment via your pharmacist. The GP will be asked to contact us if they have concerns about you receiving this treatment due to additional information they may hold.

#### Social History

1. In a week how many units of alcohol would you drink?

.....units

(1 unit = half a pint of 4% beer or 125ml (small glass) of wine or a single 25ml measure of spirits)

#### Medical history

##### **Please circle yes or no to indicate your answer**

2. Have you ever been diagnosed with a seizure (fits) disorder? YES / NO
3. Has your doctor informed you that you have reduced kidney function, also called renal impairment? YES / NO
4. Do you have unstable cardiovascular disease e.g. unstable angina, and/or are awaiting treatment for a heart condition? YES / NO
5. Have you had any cardiovascular events in the last 3 months such as a heart attack, stroke, angina attacks, TIA (mini stroke), arrhythmias (an irregular heartbeat)? YES / NO
6. Are you currently being treated for a mental health condition? YES / NO

7. Do you have a history of any of the following mental health conditions (or any other severe mental health conditions): severe depression, schizophrenia, psychosis, bipolar disease or suicidal thoughts/attempts? YES / NO
8. Have you been referred to or are under investigation/supported by a psychiatrist or mental health team? YES / NO
9. Are you pregnant, possibly planning a pregnancy or breastfeeding? YES / NO / N/A
10. Do you have a history of Stevens-Johnson Syndrome or Erythema Multiforme?  
YES / NO

Medication history

Please provide a list of your current medication, including an herbal remedy and purchased medicines:

Please provide a list on any allergies or adverse reactions you have had to medicines.

Patient name (please print): .....

Signature: ..... Date: .....

I confirm that the information provided above is a true reflection and I also consent to information being shared with my GP and Pharmacist.