

## Patient Group Direction (PGD) for the supply of Varenicline (Champix<sup>®</sup>) tablets

By authorised PGD accredited community pharmacists working in Hampshire County Council for **Smoking Cessation Support** as part of the “Smokefree Hampshire” service.

Version 1.0

<b>Issued on:</b>	1 <sup>st</sup> March 2020
<b>Expiry date:</b>	30 <sup>th</sup> September 2021

### **PATIENT GROUP DIRECTIONS – under Human Medicines Regulations 2012**

A PGD is a specific written instruction for the supply or administration of named medicines in an identified clinical situation. It applies to groups of patients or other service users who may not be individually identified before presentation for treatment. It is drawn up locally by doctors, pharmacists and other appropriate professionals, and authorised by the relevant appropriate body.

### **Change History**

<b>Version</b>	<b>Changes from previous approved PGD</b>	<b>Date of review</b>
V1	Nil, this is the first original version	Feb 2020

<b>1. Characteristics of persons authorised to operate this PGD</b>	
<b>Qualification required</b>	<ul style="list-style-type: none"> <li>Accredited pharmacists within an approved community pharmacy. Pharmacists must be registered with the General Pharmaceutical Council (GPhC).</li> </ul>
<b>Initial training</b>	<ul style="list-style-type: none"> <li>Pharmacists will undergo basic training on PGDs and their use.</li> </ul>
<b>Competency assessment</b>	<ul style="list-style-type: none"> <li>Pharmacists will complete the paper declaration of competency prior to providing this service as outlined in section: 6.</li> </ul>
<b>On-going training and competency</b>	<ul style="list-style-type: none"> <li>Pharmacists must ensure that their clinical knowledge is kept up to date within this area of practice. This will be achieved through PGD training and ensuring that they are aware of current literature (e.g. SPCs). Pharmacists must be aware of and work within the current medicines policy and be competent in the supply of Varenicline.</li> </ul>
<b>2. Clinical Condition to which the PGD applies</b>	
<b>Clinical condition or situation to which this PGD applies</b>	<ul style="list-style-type: none"> <li>Patients accessing the “Smokefree Hampshire” Specialist Smoking Cessation Service who would benefit from pharmacological treatment with Varenicline following appropriate clinical assessment by the pharmacist.</li> </ul>
<b>Criteria for inclusion</b>	<p>Patient meets <b>all</b> of the following criteria:</p> <ul style="list-style-type: none"> <li>Dependent tobacco users identified as sufficiently motivated to quit with Varenicline or are allergic to nicotine or any excipients of Nicotine Replacement Therapy products.</li> <li>One of the following: 1. a resident of Hampshire County Council 2. is registered with the Hampshire GP surgery or works within Hampshire? (excluding Soton City, Portsmouth City, IOW).</li> <li>The patient agrees to receive face to face behavioural support from the “Smokefree Hampshire” service advisors every week in the stop smoking clinics.</li> <li>Patients aged 18 years and over.</li> <li>Patient consent has been obtained for treatment and recorded.</li> <li>Patient has consented for information to be shared with their GP, “Smokefree Hampshire” service as recorded on the Quit Manager, along with forms 1, 2, and 4 with the stop smoking advisor and PGD accredited pharmacist (see appendix: A for supplementary forms on page:15).</li> <li>“Smokefree Hampshire” service stop smoking advisor will give form 5 to the patient based on their progression through their quit attempt. Patient must attend their nominated PGD accredited Varenicline</li> </ul>

	<p>pharmacy where they will be seen by the PGD accredited pharmacist.</p> <ul style="list-style-type: none"> <li>● A full medical history is taken and documented and there are no contraindications for treatment with Varenicline (see exclusion criteria).</li> <li>● Supplies after the first titration pack can only be made if the client continues to attend the “Smokefree Hampshire” Specialist Smoking Cessation Service sessions on a weekly basis for a face to face consultation with the stop smoking advisor. The supplying pharmacist will be notified of this through the provision of form 5 for maintenance supplies, which will be issued by the stop smoking advisor on a fortnightly basis.</li> <li>● “Smokefree Hampshire” service stop smoking advisor must not hesitate to contact the pharmacist through telephone or email if required to discuss the patient’s progression through the quit attempt along with any relevant issues or concerns which may need to be highlighted.</li> <li>● Pharmacists are working as part of the wider healthcare team providing support for smoking cessation and should not feel isolated. Pharmacists can contact Solutions4Health colleagues if need be for further advice.</li> </ul>
<p><b>Criteria for exclusion</b></p>	<p>Patient is excluded for one or more of the following reasons:</p> <ul style="list-style-type: none"> <li>● Tobacco users not sufficiently motivated to quit or use Varenicline.</li> <li>● Patient has had an unsuccessful attempt to quit using Varenicline on the programme in the last 6 months.</li> <li>● Patient is under the age of 18.</li> <li>● Hypersensitivity to Varenicline or any of the product excipients (check manufacturer’s SPC for details).</li> <li>● Patients with a history of, or current moderate to severe renal impairment.</li> <li>● Pregnant or breastfeeding women.</li> <li>● Valid consent not provided.</li> <li>● Patient not registered with a GP.</li> <li>● No consent to share information with GP.</li> <li>● Other licensed smoking cessation therapies (i.e. nicotine replacement therapy products) currently being used by the patient. These will need to be discontinued before patient can be considered for Varenicline.</li> <li>● Clients taking bupropion (Zyban®).</li> <li>● Clients currently obtaining varenicline on prescription or under PGD from another health professional.</li> <li>● Clients with current unstable psychiatric illness such as Schizophrenia, Bipolar disorder and major depressive disorder.</li> <li>● Patients with a history of seizures or with other conditions that lower the seizure threshold.</li> <li>● Patients with active unstable cardiovascular disease or who have had a recent cardiovascular event in the past 3 months.</li> </ul>
<p><b>Action if patient</b></p>	<p>Discuss alternative treatment options if suitable and/or offer a referral</p>

<b>declines or is not suitable based on exclusion criteria</b>	back to “Smokefree Hampshire” Specialist Smoking Cessation Service who can liaise with their GP to provide Varenicline under their supervision if clinically appropriate. Ongoing face to face behavioural support can continue with the “Smokefree Hampshire” service stop smoking advisor.
<b>Restrictions of the Varenicline PGD</b>	The PGD accredited pharmacists are subcontractors for Solutions4health and as such are only able to offer Champix <sup>®</sup> for those service users who are referred by the “Smokefree Hampshire” service only.
<b>3. Description of treatment</b>	
<b>Name of treatment</b>	Varenicline (Champix <sup>®</sup> ) 0.5mg film coated tablets. Varenicline (Champix <sup>®</sup> ) 1mg film coated tablets.
<b>Legal status of medicine</b>	Prescription Only Medicine (POM).
<b>Route of administration</b>	This is an oral formulation (tablet).
<b>Dose and frequency of administration</b>	<p>Smokers should set a date to stop smoking and treatment with Varenicline should commence 1 to 2 weeks <b>before</b> this date.</p> <p><b>Day 1-3:</b> 0.5mg (white tablets) once a day.</p> <p><b>Day 4-7:</b> 0.5mg twice a day.</p> <p><b>Day 8 – end of treatment:</b> 1mg (blue tablets) twice a day (can be reduced to 0.5mg twice a day if 1mg dose is not tolerated by the patient due to adverse effects).</p> <p><b>Varenicline dose tapering:</b> it can be commenced at week 10 to be completed by week 12 (if the client agrees). Consider supply of a starter pack at reverse dosage, with clear instructions, where patient takes:</p> <ul style="list-style-type: none"> <li>• One week of Varenicline 1mg twice daily.</li> <li>• THEN 0.5mg twice daily for four days.</li> <li>• THEN one 0.5mg tablet once daily for three days.</li> </ul> <p>The total period of treatment is 12 weeks and cannot be exceeded beyond 12 weeks.</p> <p>Tablets should be swallowed whole with plenty of water and can be taken with or without food (this will help minimise possible nausea).</p>
<b>Quantity to be supplied at each visit</b>	<p>Supply One (Regime A and B): A two-week titration pack.</p> <ul style="list-style-type: none"> <li>• The patient’s GP will be notified of the first supply of Varenicline by the PGD accredited pharmacist via form 4 (to allow the GP to intervene if necessary).</li> </ul>

	<ul style="list-style-type: none"> <li>Continuation of supply subsequent to this is based on the client continuing to attend the “Smokefree Hampshire” service sessions on a regular weekly basis. Notification confirming this to the supplying pharmacist will be made through the provision of form 5 by the stop smoking advisor for maintenance supplies, which will be issued on a fortnightly basis. It is always important to record client ID reference number from Quit Manager (supplied by the stop smoking advisor) in all correspondence to correlate the data.</li> </ul>	
	<p><b>REGIME A</b> (If product tolerated)</p> <p><b>Supply Two:</b> Two weeks (1mg x 28 tablets).</p> <p><b>Supply Three:</b> Two weeks (1mg x 28 tablets).</p> <p><b>Supply Four:</b> Two weeks (1mg x 28 tablets).</p> <p><b>Supply Five:</b> Two weeks (1mg x 28 tablets).</p> <p><b>Supply Six:</b> Two weeks (1mg x 28 tablets).</p>	<p><b>REGIME B</b> (If product not tolerated)</p> <p><b>Supply Two:</b> Four weeks (0.5mg x 56 tablets).</p> <p><b>Supply Three:</b> Four weeks (0.5mg x 56 tablets).</p> <p><b>Supply Four:</b> Four weeks (0.5mg x 56 tablets).</p>
<p><b>Duration of treatment</b></p>	<p>Maximum period of treatment is 12 weeks for 1mg twice daily and 14 weeks for 0.5mg twice daily (due to larger minimum pack size).</p> <p>The product licence permits an additional 12-week course, but this is not permitted under this PGD.</p>	
<p><b>Contra-indications</b></p>	<p>Known hypersensitivity to the active substance or any of the excipients, see SPC at:  <a href="https://www.medicines.org.uk/emc/product/7944/smpc#CONTRAINDICATIONS">https://www.medicines.org.uk/emc/product/7944/smpc#CONTRAINDICATIONS</a></p> <p>See also exclusion criteria.</p>	
<p><b>Cautions (including any relevant action to be taken)</b></p>	<p><b>Possible Effects of Stopping Smoking</b></p> <p>It should be noted that the metabolism of some drugs will be affected if a patient <u>stops smoking</u>, as the polycyclic aromatic hydrocarbons in cigarette smoke stimulates the cytochrome P450 enzymes (particularly CYP1A2). Smoking cessation reverses smoking induced CYP1A2 hepatic enzyme levels to normal, therefore increasing drug plasma concentrations.</p> <p>This effect is of clinical importance for the drugs bulleted below. <b>Additional specific advice</b> must be provided to patients receiving <b>theophylline</b>, clozapine or olanzapine as these may be significantly affected by stopping smoking. <b>Warfarin, insulin, caffeine and other medications should be monitored.</b></p> <p>For a full list of interactions refer to appropriate reference sources, including UKMI Q&amp;A 136.4, <a href="http://www.health.nsw.gov.au/tobacco/Publications/tool-14-medication-intera.pdf">http://www.health.nsw.gov.au/tobacco/Publications/tool-14-medication-intera.pdf</a></p>	

<https://www.sps.nhs.uk/wp-content/uploads/2012/10/NW20QA136.420Smoking20and20drug20interactions.doc>  
<https://www.gov.uk/drug-safety-update/smoking-and-smoking-cessation-clinically-significant-interactions-with-commonly-used-medicines>

**Advice for Patients Receiving Medications Affected by Stopping Smoking**

Patients should be advised to inform their GP, Key Worker or Specialist of their smoking cessation and to discuss possible dose reduction of any affected medications as soon as smoking ceases.

- **Cinaclet , Chlorpromazine, Methadone, Olanzapine, Ropinirole**

- **Insulin**

Patients taking insulin should be informed about the effect of stopping smoking and to be alert for signs of hypoglycaemia and encouraged to test their blood glucose more frequently.

- **Theophylline**

Patients taking theophylline should be advised to discuss their smoking cessation quit attempt with their GP at their earliest opportunity (ideally within two weeks of stopping smoking) with a view to reducing their dose when they quit. Patients should be made aware of the signs of theophylline toxicity e.g. nausea/ palpitations and to seek urgent medical advice if these occur.

- **Warfarin**

Patients taking warfarin should contact their anticoagulation clinic to inform them about stopping smoking and to arrange an earlier/ more frequent INR test.

**British National Formulary (BNF)**

- **History of psychiatric illness / psychiatric symptoms**

Care should be taken with patients who have a previous history of psychiatric illness / psychiatric symptoms (Schizophrenia, Bipolar disorder and major depressive disorder) - including any psychiatric condition requiring medication or psychotherapy in the past 5 years; these clients should be monitored closely and advised accordingly.

Pharmacists should be aware of the possible emergence of significant depressive symptoms in clients undergoing a smoking cessation attempt.

Clients should be advised to discontinue treatment and seek prompt medical advice if they develop agitation, depressed mood of concern, or suicidal thoughts.

Depressed mood, rarely including suicidal ideation and suicide attempt, may

	<p>be a symptom of nicotine withdrawal. In addition, smoking cessation, with or without pharmacotherapy, has been associated with exacerbation of underlying psychiatric illness (e.g. depression).</p>
<p><b>Drug interactions</b></p>	<p>Trial data shows no clinically meaningful drug interactions.</p> <p>No dosage adjustment of Varenicline or co-administered medicinal products is recommended.</p> <p>Consult manufacturer's SPC at:  <a href="https://www.medicines.org.uk/emc/product/7944/smpc">https://www.medicines.org.uk/emc/product/7944/smpc</a> for further information and see the caution section above along with inclusion and exclusion criteria and also check BNF at  <a href="https://bnf.nice.org.uk/drug/varenicline.html#indicationsAndDoses">https://bnf.nice.org.uk/drug/varenicline.html#indicationsAndDoses</a></p>
<p><b>Side effects</b></p>	<p><b>Very common (&gt;= 1 in 10) side effects:</b></p> <ul style="list-style-type: none"> <li>• Nausea - The most common side effect (about 30% of patients). This can be reduced by taking the tablet after food and with a full glass of water;</li> <li>• Nasopharyngitis;</li> <li>• Insomnia/abnormal dreams;</li> <li>• Headache.</li> </ul> <p><b>Common (&gt;=1in100 to &lt; 1/10):</b></p> <ul style="list-style-type: none"> <li>• Appetite changes, increased weight;</li> <li>• Dry mouth/taste disturbances/GIT disorders;</li> <li>• Drowsiness;</li> <li>• Dizziness/ Somnolence;</li> <li>• Dyspnoea/ cough/ bronchitis, sinusitis;</li> <li>• Joint, muscle, back, chest pain, toothache;</li> <li>• Fatigue;</li> <li>• Abnormal liver function tests;</li> <li>• Rash / Pruritus.</li> </ul> <p><b>Uncommon and may be symptomatic of nicotine withdrawal (see below):</b></p> <ul style="list-style-type: none"> <li>• Abnormal thinking;</li> <li>• Mood Swings.</li> </ul> <p><b>Frequency not known</b></p> <ul style="list-style-type: none"> <li>• Loss of consciousness</li> </ul> <p>For the full list of side effects refer to the Varenicline SPC : <a href="https://www.medicines.org.uk/emc/product/7944/smpc">https://www.medicines.org.uk/emc/product/7944/smpc</a></p> <p>Depressed mood, rarely including suicidal ideation and suicide attempt may be a symptom of nicotine withdrawal.</p>

	<p>Clinicians must be aware of possible emergence of serious neuropsychiatric symptoms in patients attempting to quit smoking with or without treatment. If serious neuropsychiatric symptoms occur whilst on Varenicline treatment, patients should be advised to discontinue Varenicline immediately and seek prompt medical advice.</p> <p>Care should be taken with patients who have a history of psychiatric illness; these patients should be advised accordingly.</p> <p>Refer to the BNF and the SPC for more details.</p> <p>The Medicines and Health Products Regulatory Agency (MHRA) asks that all suspected reactions are reported through the Yellow Card Scheme at: <a href="http://www.mhra.gov.uk/yellowcard">www.mhra.gov.uk/yellowcard</a> or via the yellow card found at the back of the current edition of the BNF.</p> <p>If reporting via the latter, please post the yellow card to: FREEPOST YELLOW CARD (no other address details required).</p> <p>ADRs should also be reported to the “Smokefree Hampshire” stop smoking advisor, who will liaise with the patient’s GP to notify them (following client’s consent).</p>
<b>Storage</b>	<p>Blisters: Store below 30°C HDPE Container: This medicinal product does not require any special storage conditions</p>
<b>Labelling</b>	<p>The product must be labelled as for a dispensed medicine and bear all relevant cautionary wording as stated in the BNF.</p> <p>Titration packs must bear the instruction to “take as directed on enclosed leaflet” and other packs to “Take one tablet twice a day”.</p>
<b>Written information to be given to patient or carer</b>	<p>A copy of the manufacturer’s patient information leaflet must be supplied.</p>
<b>Follow-up advice to be given to patient or carer</b>	<p>Advice to patients should include specific product advice on dosage, method of administration and side effects. Product should be labelled according to legal requirements.</p> <p>Women of childbearing age should be advised to avoid becoming pregnant during treatment with Varenicline.</p> <p>Patients should be made aware of the following possible adverse reactions:</p> <p><b>Altered reaction to alcohol:</b> patients may experience increased drunkenness,</p>



unusual or aggressive behavior as well as experiencing no memory of things.

**Depressive Illness:** Clinicians should be aware of the possible emergence of depressive symptoms in patients undertaking a smoking cessation attempt and advise patients accordingly. Patients should be advised to seek medical advice if symptoms occur. It is important that the patient is encouraged to declare any current or history of mental illness (see information on exclusion criteria). Pharmacists should be aware of the possible stigma associated with the declaration of such conditions and therefore ensure that the patient has sufficient privacy during the initial consultation to facilitate such conversations.

**Cardiovascular symptoms:** Patients should inform their GP, smoking cessation advisor and the pharmacist of any new or worsening cardiovascular symptoms (e.g. chest pain and tightness at rest or exertion, shortness of breath, palpitations, pain radiating to the jaw, neck, arms, lightheadedness, blurred vision, double vision, loss of vision, headache, confusion, trouble speaking, sudden trouble walking etc.) and seek immediate medical attention if they experience signs and symptoms of myocardial infarction or stroke. Immediate medical help can be sought by ringing 999 or visiting the A&E department to receive urgent medical attention and care.

**Hypersensitivity reactions:** If the patient experiences swelling of the face, mouth (tongue, lips, gums), neck (throat, larynx) or extremities, whilst taking Varenicline they should discontinue treatment and seek medical advice immediately.




**Cutaneous reactions (rare):** If the patient develops a rash or skin reaction whilst taking Varenicline, they should discontinue treatment at the first sign and seek medical advice immediately.

It is important to make sure that the patient understands the following points:

- Varenicline is not a **magic cure**: effort and determination are crucial;
- It works by acting on the parts of the brain which are affected by nicotine in cigarettes;
- It does not remove all the temptation to smoke, but it does make abstinence easier (it takes the edge off the discomfort by reducing the severity of tobacco withdrawal symptoms);
- About a third of clients may experience mild nausea usually about 30 minutes after taking Varenicline. This reaction often diminishes gradually over the first few weeks, and most patients tolerate it without problems;
- If the patient is finding the side effects intolerable, they should seek advice from their Stop Smoking Adviser or Pharmacist.

	<p><b>The following additional general advice should also be given:</b></p> <ul style="list-style-type: none"> <li>• The importance of follow-up and how to obtain further supplies;</li> <li>• Possible changes in the body on stopping smoking e.g. weight gain;</li> <li>• Varenicline may cause drowsiness and dizziness. If affected the patient should be advised not to drive or operate machinery;</li> <li>• If the patient forgets to take Varenicline, they should not take a double dose to make up for the one they missed. It is important they take it as soon as they remember but if it is almost time for the next dose, they should not take the tablet they have missed;</li> <li>• At the end of treatment, discontinuation of Varenicline has been associated with an increase in irritability, urge to smoke and/or insomnia in up to 3% of patients.</li> </ul> <p><b>The major reasons for Varenicline failure are:</b></p> <ul style="list-style-type: none"> <li>• Unrealistic expectations</li> <li>• Lack of preparation for the fact that tablets may cause nausea</li> <li>• Insufficient support from trained smoking cessation advisor</li> </ul> <p>Patients will be seen by the “Smokefree Hampshire” service weekly for up to twelve weeks after the quit date and by the Pharmacist at each supply of Varenicline.</p> <p><b>Criteria for stopping Varenicline treatment immediately:</b></p> <ul style="list-style-type: none"> <li>• The patient does not want to continue treatment.</li> <li>• The “Smokefree Hampshire” service or pharmacist believes that Varenicline treatment is no longer appropriate.</li> <li>• An absolute contra-indication is brought to light or develops.</li> <li>• The patient develops agitation and/or depressed mood, suicidal thoughts or other serious mood changes of concern (patient to be referred to GP for prompt medical advice).</li> <li>• The patient experiences a cardiovascular, hypersensitivity or cutaneous adverse reaction.</li> <li>• The patient experiences a side effect that is so severe as to impair quit attempt.</li> </ul>
<p><b>Informed Consent</b></p>	<p>Patient must be informed that information relating to the supply of Varenicline under a PGD needs to be passed to other health service organisations their GP and Solutions4health to ensure proper record keeping and patient safety.</p>
<p><b>Record keeping</b></p>	<p>When supplying/administering medicines using this PGD the following records must be kept:</p> <ul style="list-style-type: none"> <li>• Informed consent to share identifiable recorded information with the “Smokefree Hampshire” service, participating pharmacies and the patient/ client’s GP to ensure proper record keeping and patient</li> </ul>

	<p>safety</p> <ul style="list-style-type: none"> <li>• Name of patient/client, address, date of birth (where reasonably practical)</li> <li>• Name of GP and address</li> <li>• Diagnosis</li> <li>• Dose, form and route of administration</li> <li>• Manufacturer of product, batch number and expiry date</li> <li>• Date of treatment supply</li> <li>• Name and GPhC number of Pharmacist who supplied the medication</li> <li>• Any advice given to the patient</li> <li>• Details of any ADRs and action taken</li> </ul> <p>Pharmacists will keep a record of their consultations on supplementary paper forms and will record Varenicline supplies on form 1.</p> <p>Pharmacies must participate in an annual clinical audit if requested by the service provider.</p>
<p><b>References</b></p>	<ol style="list-style-type: none"> <li>1. HSC 2000/026 Patient Group Directions</li> <li>2. BNF <a href="https://bnf.nice.org.uk/drug/varenicline.html#indicationsAndDoses">https://bnf.nice.org.uk/drug/varenicline.html#indicationsAndDoses</a></li> <li>3. EMC <a href="https://www.medicines.org.uk/emc/product/7944/smpc">https://www.medicines.org.uk/emc/product/7944/smpc</a></li> <li>4. EMC <a href="https://www.medicines.org.uk/emc/product/266/smpc">https://www.medicines.org.uk/emc/product/266/smpc</a></li> <li>5. NMC Standards for Medicines Management (2008)</li> <li>6. NMC: The Code: Professional standards of practice and behaviour for nurses and midwives (2015)</li> <li>7. NICE MPG2 Patient Group Directions (Aug 2013) <a href="https://www.nice.org.uk/guidance/mpg2">https://www.nice.org.uk/guidance/mpg2</a></li> <li>8. <a href="#">Summary of Product Characteristics</a>; Varenicline 06/2016: Package Leaflet now updated to Include New Safety &amp; Efficacy Data from the EAGLES Clinical Trial Following Positive Opinion by CHMP1 July 2016</li> <li>9. EAGLES update <a href="https://www.ncsct.co.uk/publication_varenicline_SPC_update.php">https://www.ncsct.co.uk/publication_varenicline_SPC_update.php</a></li> <li>10. NICE TA123 – Varenicline for Smoking Cessation (<a href="https://www.nice.org.uk/guidance/ta123">https://www.nice.org.uk/guidance/ta123</a> )</li> </ol>

<b>4. Authorisation of PGD</b>			
<b>Hampshire County Council for authorisation of patient group direction for the supply of Varenicline for smoking cessation by community pharmacies</b>			
<b>Clinical authorization</b>			
<b>Name</b>	<b>Job title and organisation</b>	<b>Signature</b>	<b>Date</b>
<b>Lead Doctor: Dr Asiya Kaiser</b>	Medical officer/Clinical Lead on behalf of Solutions4Health Ltd.		20/02/2020
<b>Lead pharmacists: Darush Attar-Zadeh BPharm MFRPSII D. Hyp (Distinction), PDCHyp, PDCBHyp (Distinction), MBSCH</b>	Lead Pharmacist and Trainer, Solutions4Health.		20/02/2020
<b>Commissioner authorisation</b>			
<b>Lead commissioner, Smokefree Hampshire Service: Fatima Ndanusa</b>	Public Health Principal – Lifestyles, Hampshire County Council		24/02/20
<b>Version control</b>			
<b>PGD comes into force:</b>	1 <sup>st</sup> March 2020		
<b>PGD expires</b>	30 <sup>th</sup> September 2021		
<b>Version</b>	1.0		
<b>5. PGD development team</b>			
Darush Attar-Zadeh	Pharmacist & National Trainer Smoking Cessation		
Dr Asiya Kaiser	Clinical Lead, Solutions4Health		
Leena Sankla	Director of Public Health, Solutions4Health		

## 6. AUTHORISATION OF NAMED PHARMACISTS TO OPERATE UNDER THIS PGD

### Agreement by Pharmacist

#### Authorisation

This Patient Group Direction gives authority for:

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**(PRINT NAME OF APPROVED PHARMACIST)**

To supply Varenicline (Champix<sup>®</sup>) 0.5mg and 1mg to patients

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**(NAME OF PHARMACY)**

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**(ADDRESS)**

#### Requirements for a participating pharmacist

- To have satisfactorily completed the required training
- To have been accredited as an approved practitioner within this scheme
- To have been advised to have appropriate indemnity insurance

To maintain clinical knowledge appropriate to their practice by attending relevant study days or completing courses and to make themselves aware of appropriate current literature such as the latest Summaries of Product Characteristics.

- To act as an approved practitioner within the terms of the Patient Group Directions and Proformas and to supply accordingly
- To work in an approved pharmacy

Solutions 4 Health (“Smokefree Hampshire”) will accept responsibility for *only* the accuracy and clinical content of the Patient Group Direction and Assessment Proforma.

#### Pharmacist declaration

I have received, read and fully understand the following documents:

1. The general policy on pharmacist supply under Patient Group Directions issued by Solutions4Health
2. The relevant Patient Group Direction
3. The forms associated with Patient Group Direction

I have received the training which approved practitioners must undertake before being authorised to supply Varenicline under the relevant Patient Group Direction.

I agree to act as an approved practitioner within the terms of the Patient Group Direction and Assessment Proforma and to supply accordingly.

I understand that by agreeing to act as an approved practitioner under the Patient Group Direction and I am adjusting my scope of professional practice.

**Pharmacist Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**7. SUMMARY LIST OF ALL PHARMACISTS AUTHORISED TO USE  
THE VARENICLINE PGD**

Pharmacist	Signature	GPhC Number	Date

## Appendix: A Supporting document for the Varenicline PGD

- “Smokefree Hampshire” service 02 Flow chart for supply only and supply/advice and Champix pharmacy process map.



Flow Chart



Champix pharmacy  
process.docx

- “Smokefree Hampshire” service 03 Protocol policy of supplying Varenicline under a PGD



03 Protocol

- “Smokefree Hampshire” service Form 1 – The Pharmacy assessment and PGD Varenicline supply only form (Pharmacy use only)



Form 1

“Smokefree Hampshire” service Form 1A-Monthly claim form template (pharmacy use only)



Form 1A

- “Smokefree Hampshire” service Form 2 – Patient assessment form (Advisor use only – for information)



Form 2

- “Smokefree Hampshire” service Form 5 – Pharmacist letter of recommendation (Advisor use only)



Form 5

- “Smokefree Hampshire” service Form 4 – The GP notification of supply form (Pharmacy use only)



Form 4