Patient Group Direction (PGD) for the supply of Varenicline▼ (Champix®)

Via Accredited Pharmacists

Authorised by Stoke on Trent City Council

Document Control

Document Control	
Document name	Patient Group Direction (PGD) for the supply of Varenicline▼ (Champix®)
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Date	**Who**	**Change**	**Version**
26/1/2015	Katty Ager	Created	Version 1
30/7/2015	Rochelle Edwards	New letters-appendix 4 Incident reporting form-appendix 7	Version 1
07/10/2015	Rochelle Edwards	Appendix 3 and 4 amended	Version 1
03/11/2015	Rochelle Edwards	Miscellaneous Changes	Version 1

Overview

- It is the responsibility of the professional working under this PGD to verify that the Service User fulfils the stated criteria for supply of the treatment concerned.
- It is not appropriate to have a PGD in place that is infrequently used by health care professionals because of progressive unfamiliarity with its contents. Any healthcare professional that works to a PGD infrequently should consider whether to cease doing so.
- Varenicline▼ is a licensed Prescription Only Medicine (POM) as defined by the Medicines Act 1968 and Prescription Only Medicines (Human Use) Order 1997.
- Varenicline▼ is required to be intensively monitored and subject to special reporting arrangements for adverse events (Black triangle medicine). *Nearly seven years after launch, Varenicline▼ is still considered to require this restriction.*
- Recent NICE guidance on appropriate use of PGDs requires that a black triangle medicine is included in a PGD only when clearly justified by best clinical practice and that this status is clearly indicated on the PGD.
- Clinical indications, Contraindications, and Cautions are as set out in the Summary of Product Characteristics
- Inclusion and Exclusion criteria are summarised within the PGD
- "Off Label" use is not supported by the PGD

Supporting Documentation

- NICE technology appraisal guidance 123, Varenicline for smoking cessation. https://www.nice.org.uk/guidance/ta123/resources/guidance-varenicline-for-smoking-cessation-pdf
- NICE public health guidance 10, Smoking cessation services. https://www.nice.org.uk/guidance/ph10/resources/guidance-smoking-cessation-services-pdf
- NCSCT, Local Stop Smoking Services, Service and Delivery Guidance 2014. http://www.ncsct.co.uk/usr/pub/LSSS_service_delivery_guidance.pdf
- NCSCT, Varenicline: effectiveness and safety http://www.ncsct.co.uk/usr/pub/Varenicline_effectiveness_safety.pdf
- UKMi, Medicines Q&A's, Which medicines need dose adjustment when a patient stops smoking? UKMi 136.

Professional Indemnity

The Pharmacist should be a full registered member of the General Pharmaceutical Council (GPhC) and must work within their professional code of ethics at all times. Membership of the Royal Pharmaceutical Society (RPS) is highly recommended. The Pharmacist must ensure their professional indemnity cover is provided by the National Pharmaceutical Association (NPA) or other organisation which has confirmed that this activity is included in their policy.

Clinical Governance

The Pharmacist will have in place comprehensive and demonstrative system of clinical governance. The pharmacy will have in place a standard operating procedure (SOP) for the provision of this service.

Staff Characteristics and training requirements

- Pharmacist registered with General Pharmaceutical Council,
- Pharmacists registered with the Centre for Pharmacy Postgraduate Education (CPPE)
- Working within a Stoke on Trent pharmacy where there is an agreement with Stoke on Trent County Council to supply Varenicline▼ under a PGD.

The Pharmacist must be able to demonstrate that they have the necessary competencies to supply Varenicline under a PGD, this can be demonstrated through completion of the Declaration of Competence self-assessment tool on the CCPPE website. In addition they must have completed the local Varenicline▼ training programme.

This PGD will only apply whilst the Pharmacist is employed or contracted/working at the time in an accredited Pharmacy.

Accredited Pharmacies will have a suitable private consultation room / area which is available for all Service User consultations.

The Pharmacist should be aware of any change to the recommendations for the medicine listed. It is the responsibility of the individual to keep up-to-date with continued professional development and to work within the limitations of individual scope of practice.

Reimbursement and Prescription Charges
Pharmacists will be paid £15 for the first supply of Varenicline▼ and £2.50 for subsequent supplies. The data will be collected on a PharmOutcomes a data management system commissioned by the Authority.
Prescription charges will be collected where applicable. Where Service Users are exempt from prescription charges Pharmacists will need to ask Service Users if they have evidence to support their exemption status.

1. Reason for introducing PGD		
For accredited Pharmacists to supply Varenicline▼ within its licensed indications as an option for smokers who have expressed a desire to quit smoking. Service Users can be supplied Varenicline▼ via an accredited Pharmacist if: • The Pharmacist is accredited by Stoke-on-Trent City Council to provide stop smoking support (this includes subcontracted Pharmacist). • If a Service User is accessing a stop smoking service accredited by Stoke-on-Trent City Council for behavioral support and wishes to use Varenicline▼ to aid their quit attempt		
2. Clinical Condition or situation to which this PGD applies		
2.1	Define condition/situation	Varenicline▼ as an option for Service Users wishing to quit smoking whilst receiving behavioural support from an Accredited Stop Smoking Provider.
2.2	Criteria for inclusion ALL MUST APPLY	• Service Users who have set a target quit date with an Accredited Stop Smoking Provider • Service Users aged 18 years of age and over • Tobacco users identified as sufficiently motivated to quit • Tobacco users who are receiving support to stop smoking with a Stoke on Trent accredited Stop Smoking Service and who have a Varenicline▼ initial referral letter Appendix 1a and Appendix 1b for subsequent supplies • 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 (see Criteria for exclusion and Criteria for cautions). Refer to Appendix 2 for Assessment to Supply Varenicline▼ • Patient consent has been obtained and recorded
2.3	Criteria for exclusion	• Tobacco users not sufficiently motivated to quit or use Varenicline▼ • Service User's under 18 years of age • Sensitivity to Varenicline▼ or any of its excipients

		• Pregnancy/ Breastfeeding • Service User's already receiving Varenicline▼ prescribed by GP • Service User's already using other smoking cessation pharmacotherapies • Patient with history of renal impairment or end stage renal disease as decreased clearance by kidney increases side effects. • Service User's with history of epilepsy or history of fits or seizures • Substance misuse patients • Service User's who have experienced serious or significant side effects from a previous course of Varenicline▼ • Service User's with active or history of psychiatric illness. *The MHRA have warned that there is a possible link between Varenicline▼ and psychiatric adverse events, particularly agitation, depression, and suicidal ideation. There is no strong epidemiological evidence from the clinical trials or monitoring data to suggest a causal link and no putative pharmacological mechanism to suggest causality.* • Service Users who are planning to use an electronic nicotine delivery device (ENDS) as part of their quit attempt. (inc appendix on e-cig) Please see section 2.6 for action when a Service User is excluded.
2.4	Criteria for cautions [to include consideration of concurrent medication]	No clinically significant drug interactions have been reported. Since metabolism of Varenicline▼ represents less than 10% of its clearance, active substances known to affect the cytochrome P450 system are unlikely to alter the pharmacokinetics of Varenicline▼ and therefore dose adjustment is not required. However, patients should be informed that physiological changes resulting from smoking cessation, with or without treatment with Varenicline▼, may alter the pharmacokinetics or pharmacodynamics of some medicinal products for which dose adjustment may be necessary. Examples include • Theophylline • Warfarin • Insulin. The Service Users GP will be notified of every initial supply of Varenicline▼ within 2 working days(see appendix 3 for exemplar information), this will be done via PharmOutcomes using secure nhs.net accounts

		when the Service Users data is saved on PharmOutcomes. On the rare occasion where no nhs.net account is available to PharmOutcomes the Pharmacists will be informed by the system and must make alternative arrangements to send the information (within 2 working days). In addition, if a Service User is a diabetic or is taking theophylline/aminophylline or warfarin, the letter provided in appendix 4 must be completed and given to the Service User to take to their GP or relevant clinic to notify them of their quit attempt/use of Varenicline▼ For further information please refer to UKMi "Which medicines need dose adjustment when a patient stops smoking?" UKMi Q&A 136.4
2.5	Service User consent-	Consent will be obtained at the initial consultation and then recorded on PharmOutcomes (approved Local Authority data management system). This will include • consent to treatment and follow up • details to be shared with GP or other relevant healthcare professional, Stop Smoking Provider, Local Authority and any other relevant third party organisation. Treatment should not proceed if the Service User does not consent to ALL of the above
2.6	Action if Service User excluded	If the GP has informed the Pharmacist that the Service User should not receive the medication, as a result of the email notification or letter (described in section 2.4) then the Pharmacist should use the letter in Appendix 5 to inform the Service User. Pharmacists which are also Accredited Stop Smoking Providers should offer Service Users the option of NRT. Where a Service User has been referred by an Accredited Stop Smoking Service they should be referred back to the service. Pharmacists should notify the Accredited Stop Smoking Provider by telephone (this will be on each referral letter) within 2 working days with an explanation as to why the Service User was excluded. This should be recorded onto PharmOutcomes. Document action in patient medication record (PMR).
2.7	Action if treatment declined by Service User	Pharmacists providing Stop Smoking Services should offer other available smoking cessation options if appropriate. Where a Service User has been referred by an

		Accredited Stop Smoking Service they should be referred back to the service. Pharmacists should notify the Accredited Stop Smoking Provider by telephone within 2 working days with an explanation as to why the treatment was declined. This should be recorded onto PharmOutcomes. Document action in patient medication record (PMR)
2.8	Action if Pharmacist is unavailable to supply subsequent supplies of Varenicline▼	After the initial supply of Varenicline▼ the Service User should normally receive subsequent supplies from the same Pharmacy by an accredited Pharmacist. If this is not possible for example due to sickness absence then the Service User can attend another participating Pharmacy. In this situation the new Pharmacist will need to re-assess the suitability for Varenicline▼. The Pharmacist will be reimbursed at the initial supply price of £15 to reflect this work.
3.	**Description of treatment.**	
3.1	Generic name of medicine and form (e.g. tablets)	Varenicline▼ (Champix®) 0.5mg film coated tablets Varenicline▼ (Champix®) 1mg film coated tablets
3.2	Legal status POM/P/GSL	Prescription Only Medicine – subject to intensive monitoring requirements (Black Triangle Drug)
	Licensed or unlicensed use [If unlicensed state rationale for use]	Licensed
3.3	Precautions, facilities & supplies	Store in a cool dry place below 30 degrees Celsius. Order supplies from licensed pharmacy wholesalers.
3.4	Dose and Frequency	**In all circumstances dosing should follow the recommendations in the Varenicline▼ Summary of Product Characteristics** **http://www.medicines.org.uk/emc** **Days 1 – 3:** 0.5 mg (white tablets) once daily **Days 4 – 7:** 0.5 mg(white tablets) twice daily **Week 2 to week 12:** 1 mg (light blue tablets) twice daily Patients who cannot tolerate the adverse effects of Varenicline▼ can have the dose lowered temporarily or permanently to 0.5mg (white tablet) twice daily. (See BNF 4.10.2) **Extending course to reduce risk of relapse:** The normal 12-week course can be repeated in abstinent individuals to reduce risk of relapse. Approval must be sought from the Authority for extending the treatment course beyond 12weeks. Approval will then trigger the additional information to become available on PharmOutcomes and enable the

		relevant data to be captured. **Dose tapering** In patients with a high risk of relapse, dose tapering may be considered at the end of the standard 12 weeks of treatment **Quit date** All Service Users must have set a target quit date before the commence treatment. Treatment should be started 1-2 weeks before the actual quit date.
3.5	Route / method of administration	Oral
3.6	Total dose and number of times treatment can be administered; state time frame	• Service Users should be initially supplied a 14 day initiation pack and should have set a target quit date 7 to 14 days after initiation • Subsequent supplies using the 14-day prescription packs, complete with Patient Information leaflet, should be provided throughout the quit attempt. • The normal treatment course is 12 weeks • An additional course of 12 weeks treatment of Varenicline▼ at either 0.5mg or 1 mg twice daily (depending on previous dose) may be considered with permission from commissioner • The maximum length of treatment is 24 weeks
3.7	Instructions on identifying, managing & reporting adverse drug reactions	For Service Users experiencing **mild** adverse effects after dose increase to 1mg twice daily, consider a temporary or permanent dose lowering to 0.5 mg twice daily. (See BNF 4.10.2) Review at next scheduled appointment **Very Common and Common Adverse Reactions of Varenicline▼.** • Infections and infestations Very common-Nasopharyngitis Common-bronchitis, sinusitis • Metabolism and nutrition disorders Common-weight increased, decreased appetite, increased appetite • Psychiatric Disorders Very Common-abnormal dreams, insomnia • Nervous System Disorders Very Common-headaches Common-somnolence, dizziness, dysgeusia • Respiratory, thoracic and mediastinal disorders Common-Dysponea, cough • Gastrointestinal disorders Very Common-Nausea Common-Gastroesophageal reflux disease, vomiting constipation, diarrhoea, abdominal distension, abdominal pain, toothache, dyspepsia, flatulence, dry

		mouth • Skin and subcutaneous tissue disorders Common-rash, pruritus • Musculoskeletal and connective tissue disorders Common-Arthralgia, myalgia, back pain • General Disorders and administration site conditions Common-chest pain and fatigue • Investigations Common-liver function test abnormal **For comprehensive information please consult the Summary of Product Characteristics which can be found at https://www.medicines.org.uk/emc/medicine/19045** **Symptoms of Stopping Smoking** Smoking cessation with or without treatment is associated with various symptoms. For example, dysphoric or depressed mood; insomnia, irritability, frustration or anger; anxiety; difficulty concentrating; restlessness; decreased heart rate; increased appetite or weight gain have been reported in Service Users attempting to stop smoking. No attempt has been made in either the design or the analysis of the studies to distinguish between adverse events associated with study drug treatment or those possibly associated with nicotine withdrawal. Service Users should be asked at every appointment about their mood and the answer recorded on PharmOutcomes. If the Service User develops suicidal thoughts or behaviour they should be told to stop treatment and contact their GP immediately. Where the pharmacy is not the Service User's Stop Smoking Service Provider, the Pharmacist should also inform the Accredited Stop Smoking Provider. This should also be recorded on PharmOutcomes. If the Service User, family or care givers have concerns about agitation, depressed mood or changes in behaviour Varenicline▼ should be stopped immediately. Please refer to current BNF and SPC for full details. **Varenicline▼ is required to be intensively monitored and subject to special reporting arrangements for adverse events and carries a black triangle. The Pharmacist is required to report all adverse reactions to the Medicine and Health Products Regulatory Agency (MHRA) using the yellow card system. It is possible to do so online at: www.yellowcard.gov.uk**

		Any adverse reactions should be reported to the GP. A copy of the information reported using the yellow card system should also be emailed to the Authority using the following email address stopsmoking@stoke.gov.uk . This should only be anonymised data to comply with Information Governance requirements.
3.8	Written/verbal advice for Service User before/after treatment and management	• Service Users should be advised to set a quit date 7 to 14 days after initiation • The major reasons for Varenicline▼ failure are: - Unrealistic expectations - Lack of preparation for the fact that the tablets may cause nausea - Insufficient or incorrect use • It is important to make sure that the Service User understands the following points: 1. Varenicline▼ is not a magic cure - effort and determination are crucial 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 ('it takes the edge off the discomfort') 4. Varenicline▼ is safe, but about a third of Service Users may experience mild nausea some 30 minutes after taking it. This reaction usually diminishes gradually over the first few weeks, and most Service Users tolerate it without problems. If Service User is unable to tolerate due to nausea consider reducing the dose to 0.5mg or refer back to the Stop Smoking Provider. 5. Instruct on correct use and daily dose. Use mock product packaging for the explanation. Service Users should take Varenicline▼ for 7 to 14 days before stopping smoking 6. For patients who have successfully stopped smoking at the end of 12 weeks, an additional course of 12 weeks treatment with Varenicline▼ at the current dose (0.5mg or 1 mg) twice daily may be considered for maintenance of abstinence in exceptional cases with permission from the commissioner • 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 Service Users. The Pharmacist should inform the Service User accordingly and discuss or consider the need for dose tapering.

		• No clinically significant drug interactions have been reported. Since metabolism of Varenicline▼ represents less than 10% of its clearance, active substances known to affect the cytochrome P450 system are unlikely to alter the pharmacokinetics of Varenicline▼ and therefore dose adjustment is not required.
3.9	Communication with Service User's General Practice	In every case when the initial supply of Varenicline▼ is made in accordance with this PGD, the Pharmacist must inform the Service User's General Practitioner of the supply within two working days. This will be done through secure nhs.net email accounts via PharmOutcomes using secure nhs.net accounts when the Service Users data is saved on PharmOutcomes. On the rare occasion where no nhs.net account is available to PharmOutcomes the Pharmacists will be informed by the system and must make alternative arrangements to send the information (within 2 working days). (see appendix 3 for an exemplar of the information which will be sent). As per section 2.4 where a dose adjustment of current medication is required the Service User should be advised to contact their GP or appropriate clinic to discuss (use appendix 4).
3.10	Communication with Service User's Stop Smoking Service Provider	Where the pharmacy is not the Service User's Stop Smoking Service Provider, the Pharmacist should inform the Service Provider reasons for not supplying or when the Service User fails to attend an appointment Pharmacists should notify the Accredited Stop Smoking Provider by telephone within 2 working days, with an explanation as to why Varenicline▼wasn't supplied. This action should also be recorded onto PharmOutcomes.
3.11	Arrangements for referral for medical advice	Pharmacists must be able to advise Service User/parent/carer or family member what action to take in the event of the Service User experiencing any side effects and the most appropriate action (e.g. dose reduction or medical service to contact).
3.12	Information on follow-up management	Advise to seek urgent medical advice if a severe reaction to the medication occurs.
3.13	Method of recording and records management	Pharmacists should note the following when receiving referral and subsequent supply letters • Only original letters should be accepted. • An appointment should have been made with the Pharmacist prior to attending. • The letter is only valid for one month from the date of issue. If a letter is received after this then the Pharmacist should check with the Accredited Stop

		Smoking Provider that the Service User is still attending for behavioural support. • PharmOutcomes should be used to ensure the Service User has not already attended an appointment with a Pharmacist for a supply of Varenicline▼ (using unique supply reference code) • The letter should be retained, in accordance with the Data Protection Act 1998, for audit purposes. A number of fields will need to be completed on PharmOutcomes in order for payment to be processed, these include. Inputting of data should be done with 48 hours following the appointment with the Service User: • Service User's name, address, date of birth and GP details. • The accredited Provider who referred and the Advisor • Date supplied and name of the Pharmacist who supplied the medication. • Batch number and expiry date. • Reason for inclusion. • Advice given to Service User. Whether the Service User is entitled to free prescription charges and if so whether evidence has been seen. Details of any adverse drug reaction and actions taken including documentation in the Service User's medical record via GP (as well as reporting to the CSM using the 'Yellow Card' reporting system).Any paper records will need to be stored in accordance with Data Protection Act 1998.
4. Acknowledgements		
This Varenicline▼ PGD has been adapted, with permission, from Worcestershire Public Health Department part of Worcestershire County Council.		
5. Audit		
This PGD will be monitored by the Local Authority in accordance with local and national requirements for PGDs. Pharmacists accredited to supply Varenicline▼ must also regularly audit the service they are providing to ensure that the quality standards are being met.		
6. Management		
6.1	PGD Group	Andy Pickard, Pharmacy Advisor - NHS England North Midlands Staffordshire and Shropshire Dr Gill Hall, Service Development Officer - South Staffordshire LPC Tania Cork, Chief Officer - North Staffs and Stoke Local Pharmaceutical Committee Rochelle Edwards, Senior Health Improvement Specialist - Stoke-on-Trent City Council

6.2	Authorisation This PGD has been approved by:

Name and Designation	**Organisation**	**Signature**	**Date**
Dr Lesley Mountford, Director of Public Health	Stoke on Trent City Council		
Dr Manir Hussain, Head of Medicines Optimisation	Stoke on Trent Clinical Commissioning Group		10/11/15
Rochelle Edwards, Senior Health Improvement Specialist (Lead Commissioner)	Stoke on Trent City Council		

PGD for administration of Varenicline▼ tablets by Accredited Pharmacists within Stoke on Trent City Council

- I have successfully completed the training which community Pharmacists must complete before being authorised to supply Varenicline▼ under the relevant Patient Group Direction.
- I agree to maintain my clinical knowledge appropriate to my practice by attending relevant study days and courses and will make myself aware of appropriate current literature.
- I confirm my indemnity insurance covers my scope of practice.

Name	
Position	
Signature	
Date	

Appendix 1a

Initial Referral Letter for Varenicline▼

Stop Smoking Advisor to complete the following

Service User Name	
Service User Quit Manager ID Number	
Unique Supply Number-made up of the following: **2 letter initials** **QM ID** **supply number**	
GP Practice	
Stop Smoking Provider	
Signature of Stop Smoking Advisor	
Print Name	
Date	

Please ensure **all** above are completed before you give to Service User

Dear Pharmacist

The above Service User is attending stop smoking support and has expressed an interest in using Varenicline▼as an aid to quitting smoking. As an approved Pharmacist who can supply Varenicline▼ under the Stoke on Trent PGD please can you assess the Service User for clinical suitability and supply the initiation pack if appropriate. The Service User has set a quit date and agreed to attend the Stop Smoking Service for regular behavioural support and understands that the decision to supply will be made following your full assessment.

If you require any further information please contact the Stop Smoking Service Provider on _____.

Kind Regards

Notes to Pharmacist

Only original letters should be accepted.

An appointment should have been made with the Pharmacist prior to attending.

The letter is only valid for one month from the date of the letter. If a letter is received after this then the Pharmacist should check with the Accredited Stop Smoking Provider that the Service User is still attending for behavioural support.

Please use PharmOutcomes to ensure the Service User has not already attended an appointment with a Pharmacist for a supply of **Varenicline▼** (using unique supply reference code)Please retain this letter, in accordance with the Data Protection Act, 1998, for audit purposes.

Appendix 1b

Referral Letter for subsequent supplies of Varenicline▼

Stop Smoking Advisor to complete the following

Service User Name	
Service User Quit Manager ID Number	
Unique Supply Number-made up of the following: **2 letter initials** **QM ID** **supply number**	
GP Practice	
Stop Smoking Provider	
Signature of Stop Smoking Advisor	
Print Name	
Date	

Please ensure **all** above are completed before you give to Service User

Dear Pharmacist

Please could you reassess the above Service User and supply the next instalment of Varenicline▼. The Service User is continuing to attend the Stop Smoking Service for regular behavioural support and is maintaining their quit smoking status. The Service User understands that continued supply of Varenicline▼is reliant on your assessment to ensure that the medicine continues to be safe and effective.

If you require any further information please contact the Stop Smoking Service Provider on _____.

Kind Regards

Notes to Pharmacist

Only original letters should be accepted.

An appointment should have been made with the Pharmacist prior to attending.

The letter is only valid for one month from the date of the letter. If a letter is received after this then the Pharmacist should check with the Accredited Stop Smoking Provider that the Service User is still attending for behavioural support.

Please use PharmOutcomes to ensure the Service User has not already attended an appointment with a Pharmacist for a supply of **Varenicline▼** (using unique supply reference code)Please retain this letter, in accordance with the Data Protection Act 1998, for audit purposes.

Appendix 2 Pro-forma for Supply of Varenicline▼
The following information will be available on PharmOutcomes a collected at the initial session.

Factor	***Yes***	***No***	***Notes***
Has the Service User provided an original referral letter from an accredited stop smoking provider which is fully completed?			
Is the Service User already receiving Varenicline▼ from the GP?			
Is the Service User under 18 years of age?			
Is the Service User pregnant or breast feeding?			
Does the Service User suffer from renal impairment or has end stage renal disease?			
Does the Service User have an active or a history of psychiatric illness? (			
Does the Service User suffer from epilepsy or has a history of fits/seizures?			
Is the Service User on another smoking cessation pharmacotherapy or Electronic Nicotine Delivery System?			
Is the Service User on any other medication? (please refer to section 2.4 of the PGD)			
Is the Service User hypersensitive to Varenicline▼ or any of its excipients?			
Has the Service User experienced an serious side effects when using Varenicline▼during a previous quit attempt			
Is the Service User a substance misuse Service User?			
Special circumstances and any other relevant notes:			
Service User Consent: *The Service User has consented to treatment and follow up and for details to be shared with GP, Stop Smoking Provider, Local Authority and any other relevant third party organisation.*			

Treatment should not proceed if the Service User does not consent to ALL of the above

Only make a supply if you are certain that to the best of your knowledge it is appropriate to do so.

Once you are satisfied that the Service User is suitable and as consented to the above please complete the relevant fields on PharmOutcomes

Client Name and Quit Manager ID :
Date of birth:
Address:
Telephone Number:
Gp's name and address:
Exempt from prescription charges yes/no
Evidence of exemption provided yes/no
Prescription charge collected
Reason for inclusion
Name of Pharmacist
Batch number and expiry date
Date of supply
Advice given
Details of any adverse drug reaction and actions taken
Gp notification email

If treatment is declined or the Service User is excluded please ensure the Stop Smoking Provider is informed using the details provided on the initial referral letter.

Appendix 3 Exemplar of information sent to GP

Pharmacist Notification to GP of supply of Varenicline▼ will be emailed to the Service Users GP via PharmOutcomes using secure NHS email account when the patient data is saved on PharmOutcomes . Where a nhs.net email is not available to PharmOutcomes the Pharmacist will be informed by the system and must make alternative arrangements, to send the information (within 2 working days).
URGENT & CONFIDENTIAL

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.

- GP Name
- GP Address
- Patient Name
- Address
- DOB
- Telephone

Dear Doctor

I am contacting you to advise you that your patient has expressed a wish to use Varenicline▼ as an aid to stopping smoking, and a medical history has taken place to assess whether it is appropriate for them to receive it. Please note the following:

	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.
	Your patient is (delete as appropriate) diabetic / taking theophylline / aminophylline / warfarin therefore physiological changes associated with stopping smoking may necessitate a dose adjustment of their current medication.
Your patient has been advised to visit their GP if symptoms of toxicity start. Your patient has agreed to regularly attend the Stop Smoking Service for behavioural support which will increase their chance of quitting smoking successfully.	

Pharmacy Address:
Pharmacist name and contact number:
Date:

Appendix 4

Pharmacist supply of Varenicline▼

Service User Name _____

GP Practice _____

Service User Action Needed (Pharmacist to tick all that apply)**:**

Please let your GP know that you are taking Varenicline▼ if you visit them during your 12 week course.	✓
Because you take aminophylline or theophylline for your breathing it is important to contact your GP practice to make an appointment to talk about your dose. This is because when you stop smoking it changes how much theophylline or aminophylline you need. (Remember - stopping smoking is the healthy option but you do need to speak to your GP to adjust your dose).	
Because when you take warfarin stopping smoking can affect your blood levels. Please advise the clinic that you are quitting using Varenicline▼ . If you are not due to have a blood test before you start this medication it would be a good idea to ring the clinic to let them know (you may be asked to come in for an earlier blood test to keep INR levels correct)	
Because you use insulin you are advised to monitor your blood glucose levels closely. If you have any concerns about your levels please talk to your diabetic nurse/GP.	

Pharmacist signature: Pharmacy Stamp

Pharmacist name and contact number:

Appendix 5
Letter to Service User –GP decision to discontinue Varenicline▼Champix Treatment

Pharmacy Name/Stamp/Tel Number

Date/
Address:
Dear……..
RE: Request for *Varenicline▼* (Champix) to support your stop smoking attempt

Further to a recent email from your GP I would like you to stop taking the *Varenicline▼* (Champix) medication as it is not the best form of treatment for you. Please contact me if you would like to discuss this further.
Please take this letter to your Stop Smoking Advisor who will discuss other ways to help you to stop smoking. Please return any *Varenicline▼* (Champix) medication you have not used to the Pharmacy so that we can dispose of it safely.
We are sorry if this causes any problems but please continue with your attempt to stop smoking as it is the best thing you can do for the health of you and those around you.
Yours Sincerely,

Pharmacist Signature:
Print Name: