

**Patient Group Direction (PGD) for the Supply of  
VARENICLINE (Champix®) TABLETS 0.5mg & 1 mg  
for Smoking Cessation Pharmacotherapy**

by Registered, PGD Authorised and Accredited Pharmacists to Individuals Accessing the  
North Yorkshire County Council (NYCC) Stop Smoking Service from Commissioned  
Community Pharmacies within North Yorkshire County

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

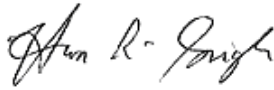
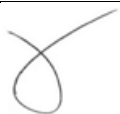

**Direction Number: - NYCC 2019/CP07**

Valid from: 1<sup>st</sup> July 2019

Review date: 1<sup>st</sup> March 2021

**Expiry date: 31<sup>st</sup> July 2021**


**This patient group direction has been developed & produced by: -**

Title	Name	Signature	Date
Medicines Optimisation Pharmacist (Lead Author) (North of England Commissioning Support)	<b>Hira Singh</b> (Senior Pharmacist)		25/05/19
Medical Director (North of England Commissioning Support)	<b>Dr James Gossow</b> (Senior Doctor)		25/05/19
Community Pharmacist (Chairman, North Yorkshire LPC)	<b>Ian Dean</b> (Senior Community Pharmacist)		25/05/19

**Development also includes contribution from:**

Emma Davis (Health Improvement Manager, NYCC)  
Jo Towler (Community Pharmacist, North Yorkshire)

**This PGD has been approved for use in North Yorkshire County Council by:**

Title	Name	Signature	Date
Director of Public Health (North Yorkshire County Council Public Health)	<b>Dr Lincoln Sargeant</b> (Authorising body Governance Authorisation)		20/06/19

# 1. Clinical Condition or Situation to Which the Direction Applies

## Indication (defines situation or condition)

- Clients for whom varenicline has been assessed as a suitable smoking cessation pharmacotherapy option presenting at a NYCC contracted smoking cessation pharmacy & who are accessing & receiving smoking cessation behavioural support from a NYCC contracted Stop Smoking Service or the NYCC Specialist Stop Smoking Service.

## Objectives of care

- Varenicline as an option for helping clients wishing to quit smoking as part of the NYCC Stop Smoking Service

## Inclusion criteria

(Only use those criteria that are specific to your authorised role & competence. Ensure appropriate consent has been obtained or a best interest decision is in place before commencing any supply).

### Clients who meet all of the following criteria:

- Dependent tobacco users identified as sufficiently motivated to quit with varenicline or are allergic to nicotine or any excipients of nicotine replacement therapy (NRT) products;
- The client is aged 18 years and over;
- Client is resident or works in NYCC or is registered with a North Yorkshire General Practitioner (GP);
- The client agrees to receive weekly behavioural support according to the agreed protocol, or who is receiving support to stop smoking with a NYCC contracted Stop Smoking Service
- A full medical history is taken and documented and there are no contraindications, or cautions or identified reasons for exclusion for treatment with varenicline (see Exclusion Criteria and referral). **Refer to Appendix 1 for Assessment to Supply Varenicline.**
- Valid patient consent to treatment with Varenicline has been obtained and recorded.
- Have consented for information to be shared with client's own GP and recorded on the Assessment to Supply Varenicline form (see Appendix 1) and sent securely (e.g. via secure email/ secure fax/) along with appropriate notification letter to GP within 72hours of supply by the accredited pharmacist. (Please refer to the SLA for the protocol of instructions on supplementary forms to be used).

## Exclusion criteria (please also refer to current SPC and latest BNF)

### Clients fulfilling one or more of the following criteria are excluded from supply under this PGD: -

- No valid consent /best interest decision in place;
- Clients under 18 years of age;
- Clients not registered with a GP;
- Patient has had an unsuccessful attempt to quit using varenicline on the smoking cessation programme in the last 6 months;
- Have any contraindication to varenicline (Champix®) tablets (**see manufacturer's Champix® SPC**)
- Hypersensitivity to any ingredient, component or excipient of varenicline (Champix®) (**refer to manufacture's SPC for details**)
- Client is already receiving varenicline from a NYCC Stop Smoking Service;
- Client is using other smoking cessation therapies. (These will need to be discontinued before patient can be considered for varenicline);
- Moderate or severe renal impairment (including elderly patients whose renal status is not known);
- Clients with a current unstable psychiatric illness, such as schizophrenia, schizoaffective disorder, bipolar disorder and major depressive disorder;
- Clients with active or history of severe and enduring mental illness (**Please also refer to cautions section**);
- Epilepsy or history of seizures; predisposition to seizures, or other medical condition that potentially lowers the seizure threshold;
- Patients with a history of unstable cardiovascular disease or who have had a cardiovascular event in the previous 3 months;
- Clients who have experienced serious or worrying side effects from a previous course of varenicline;
- If considered necessary due to medical history, the client's GP should be contacted before the client is commenced on varenicline.
- Tobacco users not sufficiently motivated to quit or to use Varenicline;
- Pregnant or breastfeeding women;
- No consent to share information with GP

## Cautions/Precautions (including any relevant action to be taken)

### Possible Physiological effects of Stopping Smoking (with or without stop smoking pharmacotherapy)

- Cigarette smoking increases the metabolism of some medicines by stimulating cytochrome P450 hepatic enzymes (particularly CYP1A2). Consequently, if a patient stops smoking the CYP1A2 hepatic enzyme levels drop back to normal and so the metabolism of some drugs will be affected by increasing their drug plasma level concentrations. As a result, the dose of theophylline, citalopram, ropinirole, and some antipsychotics (including clozapine, olanzapine, chlorpromazine and haloperidol) may need to be reduced.

This effect is of clinical importance for the drugs bulleted below. **Additional specific advice** must be provided to patients receiving **theophylline**, clozapine or olanzapine as these may be significantly affected by stopping smoking. **Warfarin, insulin, caffeine and other medications should be monitored.**

For a full list of interactions refer to appropriate reference sources, including:

- UKMI Q&A 136.4, <http://www.health.nsw.gov.au/tobacco/Publications/tool-14-medication-intera.pdf>
  - <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>
- Clients should be advised to inform their GP/specialist of their smoking cessation plan within two weeks of the initial varenicline pharmacy consultation. The standard letter to the GP (see Appendix 2) from the pharmacy (on initiation of varenicline) can also make reference to any medication identified above.

### 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 to be alert for signs of hypoglycaemia and to test their blood glucose more frequently.
- **Theophylline:**  
When the client stops smoking, metabolism of theophylline is reduced which could cause plasma theophylline levels to rise, possibly to toxic levels if the dose of theophylline is not adjusted. 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, vomiting, dilated pupils and hyperglycaemia etc. and recommended to seek urgent medical advice if these occur.
- **Warfarin**  
Patients taking warfarin should contact their anticoagulation clinic to inform them about stopping smoking & to arrange (and/or discuss the need) for more frequent / earlier INR tests.

### Patients with a history of psychiatric illness / psychiatric symptoms

The BNF states **care** should be taken with patients with 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. Clients should be monitored closely while taking varenicline/stopping smoking for exacerbations of underlying disease, including depression.

- **In line with MHRA / CHM advice** (see BNF), all patients taking varenicline (regardless of psychiatric history) should be advised to discontinue treatment and seek prompt medical advice if they develop agitation, depressed mood or suicidal thoughts.
- Pharmacists should be aware of the possible emergence of significant depressive symptoms in clients undergoing a smoking cessation attempt. If serious neuropsychiatric symptoms occur whilst on varenicline treatment, patients should discontinue varenicline immediately and contact a healthcare professional for re-evaluation of treatment.
- Depressed mood, rarely including suicidal ideation & suicide attempt, may be a symptom of nicotine withdrawal.
- Smoking cessation, with or without pharmacotherapy, has been associated with exacerbation of underlying psychiatric illness (e.g. depression). (Refer also to SPC).

### Cardiovascular events

- Patients taking varenicline should be advised to notify their doctor of new or worsening cardiovascular symptoms and to seek immediate medical attention if they experience signs or symptoms of myocardial infarction or stroke

## Action if excluded

- Discuss alternative treatment options if suitable and/or offer a referral to their GP (use letter to provide varenicline under their supervision if clinically appropriate).
- Ongoing behavioural support can continue with the NYCC or pharmacy smoking cessation advisor as appropriate.

## Circumstances in which further advice should be sought from a doctor and/or specialist

- Refer to NYCC Specialist Smoking Cessation service, or GP or Out of Hours medical practitioner if necessary following local protocols.

## Action if patient declines treatment (offer to assist the patient in this process)

- Discuss alternative treatment options if suitable and/or offer a referral to their GP to provide varenicline under their supervision if clinically appropriate. Ongoing behavioural support can continue with the NYCC or pharmacy smoking cessation advisor.
- Refer back to Smoking Cessation Adviser if appropriate.
- Record the refusal in the clinical record and document all other actions taken.

## 2. Description of treatment

### Name, strength & formulation of drug

**Varenicline (Champix®) 0.5mg film coated tablets** (manufactured by Pfizer Limited)

**Varenicline (Champix®) 1mg film coated tablets** (manufactured by Pfizer Limited)

**Varenicline (Champix®) Treatment initiation pack** (11 x 0.5mg + 14 x 1mg film coated tabs) (Pfizer Limited)

### Legal Status

**POM** – Prescription Only Medicine

### Dosage /Dose range

Refer to Dose and frequency of administration section

### Route/Method

#### Oral administration only

Tablets should be swallowed whole with plenty of water and can be taken with or without food. This will help minimise possible nausea.

## Dose and Frequency of Administration

Smokers should set a date to stop smoking. Treatment with varenicline should commence 1 to 2 weeks **before** this date.

**Day 1 to 3:** 0.5mg (white tablets) once a day

**Day 4 to 7:** 0.5mg twice a day

**Day 8 to end of treatment:** 1mg (blue tablets) twice a day for 11 weeks.

(Can be reduced to 0.5mg twice a day (temporarily or permanently) if 1mg dose is not tolerated due to adverse effects).

### Varenicline dose tapering:

This can be commenced at week 10 to be completed by week 12 (if client agrees). Consider supply of a starter pack at reverse dosage, with clear instructions, where patient takes:

- one week of varenicline 1mg twice daily
- THEN 0.5mg twice daily for four days
- THEN one 0.5mg tablet once daily for three days

**The total period of treatment is 12 weeks and cannot be exceeded beyond 12 weeks.**

If patient requires further stop smoking intervention after 12 weeks, they should be referred to their GP.

### Patients who are anxious about coming off varenicline:

These patients may have their dose lowered towards the end of treatment (maximum 12 weeks in total): Patients can be advised to taper their remaining tablets by taking one tablet daily for 3-4 days then one tablet every two days.

## Quantity to be Supplied

**Supply One:** Supply a 14 day titration pack. (Use regime A or B as clinically appropriate).

- Advisor will issue a letter of recommendation for varenicline supply to the client (see Appendix 3) to take to the nominated pharmacist.
- Clients should set a quit date 7 to 14 days after initiation and be seen weekly by their Stop Smoking Adviser for up to 12 weeks

- The patient's GP will be notified by the pharmacist of the first supply of Varenicline by using agreed letter (see Appendix 2) to allow the GP to intervene if necessary.
- At two weeks, pharmacists should confirm that patient has quit and that GP has not objected to patient receiving varenicline and that the client is receiving behavioural support sessions on a regular basis.
- All further supplies will be made at 2 weekly intervals **only** after confirmation is received from the Stop Smoking Adviser that client is continuing to attend behavioural support sessions on a regular weekly basis and should continue on varenicline.
- Notification confirming this to the supplying pharmacist will be made by the stop smoking advisor using the "Letter of recommendation for follow up varenicline supply" (see Appendix 4). The correct reference/client ID must be used in all correspondence to correlate the data at all times.
- Please refer to the SLA for documents to be used by pharmacist, pharmacy in house advisor and NYCC specialist advisor team.

### REGIME A (If product tolerated)

**Supply Two:** Two weeks (1mg x 28 tablets)  
**Supply Three:** Two weeks (1mg x 28 tablets).  
**Supply Four:** Two weeks (1mg x 28 tablets)  
**Supply Five:** Two weeks (1mg x 28 tablets).  
**Supply Six:** Two weeks (1mg x 28 tablets)

### REGIME B (If product not tolerated)

**Supply Two:** Two weeks (0.5mg x 28 tablets).  
**Supply Three:** Two weeks (0.5mg x 28 tablets).  
**Supply Four:** Two weeks (0.5mg x 28 tablets).  
**Supply Five:** Two weeks (0.5mg x 28 tablets).  
**Supply Six:** Two weeks (0.5mg x 28 tablets).

## Maximum dose & number of treatments

- **Maximum single dose:** - 1mg tablet
- **Maximum daily dose :** - 2mg
- The normal treatment course is up to 12 weeks. (See also “Dose & Frequency of Administration” section)

## Follow up treatment/action

Refer to “Dose & Frequency of administration” and “Quantity to be Supplied sections

## Storage

- **Blisters:** Store below 30°C
- **HDPE Container:** This medicinal product does not require any special storage conditions

## Labelling

- The packaging should be labelled in the manner of any prescribed medication and contain a manufacturer’s patient information leaflet.
- Titration packs must bear the instruction to “take as directed on enclosed leaflet” and other packs to “Take one tablet twice a day”

## Written information to be given to patient or carer

- A copy of the manufacturer’s patient information leaflet should be supplied..

## Follow-up advice/information to be given to patient or carer

- Clients should be advised to set a quit date 7 to 14 days after initiation
- Advice to patients should include specific product advice on dosage, method of administration and side effects. Product should be labelled according to legal requirements.
- Women of child bearing potential should be advised to avoid becoming pregnant during treatment with Varenicline.

**Patients should be made aware of the following possible adverse reactions:**

- **Altered reaction to alcohol:** patients may experience increased drunkenness, unusual or aggressive behavior, 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 be 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 of any new or worsening cardiovascular symptoms and seek immediate medical attention if they experience signs and symptoms of myocardial infarction or stroke.
- **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.

## Follow-up advice/information to be given to patient or carer - continued

### 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.

### The following additional general advice should also be given:

- The importance of follow-up and how to obtain further supplies;
- Possible changes in the body on stopping smoking e.g. weight gain;
- Varenicline may cause drowsiness and dizziness. If affected the patient should be advised not to drive or operate machinery;
- 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;
- 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.

### The major reasons for varenicline failure are:

- Unrealistic expectations;
- Lack of preparation for the fact that tablets may cause nausea;
- Insufficient support from trained smoking cessation advisor.

Patients will be seen by the NYCC Specialist Stop Smoking Service Advisor or a pharmacy in-house accredited Stop Smoking Advisor weekly for up to twelve weeks after the quit date and by the Pharmacist at each supply of varenicline.

### Criteria for stopping varenicline treatment immediately:

- The patient does not want to continue treatment;
- The North Yorkshire Stop Smoking Service or Pharmacist believes that varenicline treatment is no longer appropriate;
- An absolute contra-indication is brought to light or develops;
- 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);
- The patient experiences a cardiovascular, hypersensitivity or cutaneous adverse reaction;
- The patient experiences a side effect that is so severe as to impair quit attempt.

## Informed Consent

- Patient must be informed that information relating to the supply of varenicline under a PGD needs to be passed to other health service organisations, in particular their GP and NYCC Specialist Stop Smoking Service, to ensure proper record keeping and patient safety.
- All clients must provide written and verbal consent to contact the GP and other health care provider or if deemed necessary to obtain medical history including a list of prescribed medications or other information, which may be necessary in order for an advisor/clinician or a pharmacist to make an informed decision about commencing varenicline treatment.
- If client declines information being shared with their GP then it will not be possible to supply varenicline under this PGD.

## 3. Further Aspects of Treatment

### Drug Interactions

- No clinically meaningful 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.
- No dosage adjustment of varenicline or co-administered medicinal products is recommended.

See [manufacturer's SPC](#) for further information. See also caution section above along with inclusion and exclusion criteria.

### Relevant Warnings

**Relevant Warnings:** - See [manufacturer's SPC](#) and current BNF for full details of all potential adverse effects.

- Depressed mood, rarely including suicidal ideation and suicide attempt may be a symptom of nicotine withdrawal.
- 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.
- Care should be taken with patients with a history of psychiatric illness and patient should be advised accordingly.

### Potential Adverse Effects

#### Potential Adverse Effects/:

Please refer to the varenicline SPC: <http://www.medicines.org.uk/emc/medicine/19045> or BNF (<http://www.bnf.org.uk>) for full list of side effects.

Use the Yellow Card System to report adverse drug reactions directly to the MHRA.

<b>Very common &amp; common reactions</b>	<ul style="list-style-type: none"><li>• Nausea (about 30% of patients affected). This can be reduced by taking the tablet after food and with a full glass of water;</li><li>• Headache;</li><li>• Sinusitis;</li><li>• Insomnia;</li><li>• GIT disorders;</li><li>• Arthralgia, myalgia,</li><li>• Abnormal liver function tests;</li></ul>	<ul style="list-style-type: none"><li>• Nasopharyngitis;</li><li>• Appetite changes;</li><li>• Abnormal dreams;</li><li>• Dizziness;</li><li>• Back pain;</li><li>• Rash / Pruritus.</li></ul>	<ul style="list-style-type: none"><li>• Bronchitis;</li><li>• Increased weight;</li><li>• Dry mouth, taste disturbances;</li><li>• Somnolence; Dyspnoea/ cough/</li><li>• Chest pain, fatigue;</li></ul>
<b>Uncommon effects</b> (and may be symptomatic of nicotine withdrawal)	<ul style="list-style-type: none"><li>• Abnormal thinking; Mood Swings.</li><li>• Depressed mood, rarely including suicidal ideation and suicide attempt may be a symptom of nicotine withdrawal</li></ul>		

This list is not exhaustive. Please also refer to current BNF and manufacturers SPC for details of all potential adverse reactions

### Identification and Management of Adverse Reactions

- Patient / Carer / Guardian requested to report side effects to Healthcare professional and/or GP
- Refer to doctor if appropriate
- Document in the Patient Medication Record (PMR), in relevant NYCC documentation and inform GP.



## Reporting Procedure of Adverse Effects

- See manufacturers Summary of Product Characteristics for details of all potential adverse reactions.
- Client to report any suspected ADRs believed to be associated with varenicline (Champix) tablets to a Healthcare Professional or directly using the Yellow Card system.

Clients and Healthcare Professionals can log ADRs directly via the MHRA website (<http://yellowcard.mhra.gov.uk/>) or call freephone 0808 100 3352 (10am to 2pm Monday-Friday only), or via the yellow card found at the back of the current edition of the BNF. please post the yellow card to: FREEPOST YELLOW CARD (no other address details required).

- ADRs should also be reported to the North Yorkshire Stop Smoking Service and the patient's GP.

## Additional Information and Facilities

- Have access to the current PGD, latest manufacturer's Summary of Product Characteristics (SPC) & BNF.

## Communication with client's General Practice & Stop Smoking Advisors

- In every case when the **initial supply** of varenicline is made in accordance with this PGD, the pharmacist must inform the client's General Practitioner (GP) of the supply within two working days. (See Appendix 2).
- Smoking advisors will refer clients to the pharmacist provider using "letter of recommendation" (see Appendix 3).
- Pharmacist provider will notify the NYCC Specialist Stop Smoking Service (and the pharmacy stop smoking advisor where behavioural support is being provided in-house) of *Varenicline assessment* and of *Supply One or Non-Supply* through PharmOutcomes or as defined in the SLA.
- Stop smoking Advisor will provide behavioural support and notify pharmacist of attendance for follow up supplies of varenicline using the letter of recommendation for follow up of varenicline supply - form 5A (See Appendix 4).

## Arrangements for Referral to Medical Advice

- Refer to NYCC Specialist Smoking Cessation Service or GP as appropriate

## Records

All details to be recorded and be retained according to local, legal and professional obligations.

**When supplying/administering medicines using this PGD the following records must be kept :**

- Informed consent to share identifiable recorded information with the North Yorkshire Stop Smoking Service, participating pharmacies and the patient/ client's GP to ensure proper record keeping and patient safety;
- Name of patient/client, address, date of birth (where reasonably practical);
- Name of GP and address (if available);
- Diagnosis; Dose, form and route of administration;
- Manufacturer of product, batch number and expiry date;
- Date of treatment supply;
- Name and GPhC number of Pharmacist who supplied the medication;
- Any advice given to the patient;
- Details of any ADRs and action taken.

Pharmacists are required to keep a record of the consultation on PharmOutcomes and relevant supplementary forms (see Appendices section) and to make a record of supply in the Patient Medication Records (PMR). The supply of varenicline should also be recorded on PharmOutcomes.

***Pharmacies must participate in annual clinical audit if requested by the commissioner***

## Documents to be used in conjunction with the PGD

- See Appendix 1 - 6

## References

1. **NHS Executive HSC 2000/026** (9<sup>th</sup> August 2000): Patient Group Directions [England only].
2. **BNF** Current Edition
3. **RPS**: Professional guidance on the safe and secure handling of medicines (December 2018)  
<https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines>
4. Declaration of competence for public health pharmacy services <https://www.cppe.ac.uk/services/declaration-of-competence>
5. **RPS & RCN**: Professional Guidance on the Administration of Medicines in Healthcare Settings (2019). <https://www.rpharms.com>
6. **NICE** MPG2 Patient Group Directions (Aug 2013) <https://www.nice.org.uk/guidance/mpg2>
7. **NICE** TA123 – Varenicline for Smoking Cessation (<https://www.nice.org.uk/guidance/ta123> )
8. Pfizer Limited, Champix 0.5mg and 1mg tablets – **Summary of Product Characteristics**, 21/08/2018 (accessed from Electronic Medicines Compendium on 25/02/2019).
9. Package Leaflet now updated to Include New Safety & Efficacy Data from the EAGLES Clinical Trial Following Positive Opinion by CHMP1 July 2016 ([https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(16\)30272-0/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)30272-0/fulltext) )

## 4. Characteristics of Healthcare Professional using this PGD

**Only those pharmacists that have been specifically authorised by their clinical lead/supervisor/manager or by self-declaration may use this PGD for the indications defined within it.** You may only supply or administer medicines under a PGD as named individuals.

### Qualification/registration requirements

Accredited pharmacists currently registered with the General Pharmaceutical Council (GPhC) of Great Britain.

### Additional requirements (applies to all staff)

- Competency in the use of PGDs.
- Has read & understood this PGD and has assessed themselves as competent ideally using the *NICE Competency Framework for health professionals using Patient Group Directions* [NICE PGD resources](#).
- Pharmacist with appropriate underpinning knowledge to competently undertake the clinical assessment of patients leading to treatment according to the indications listed in this PGD.
- The pharmacist must complete their Declaration of Competence Certificate (DOC) and required training as part of the DOC, as defined by the Centre for Pharmacy Postgraduate Education (CPPE) and repeat their [CPPE declaration of competence](#) every 3 years (Pharmacists should register their DOC on the CPPE website).
- Understands their professional duties in terms of confidentiality.
- To have access to PharmOutcomes.
- Have completed all relevant training as defined by NYCC service level agreement (SLA) & NCSCT (e.g. on line modules)
- Pharmacists to retain all training documentation. (Maintenance of accreditation is as defined by CPPE/NYCC).
- The pharmacist must ensure that the pharmacy they are working in is an NYCC approved stop smoking provider of varenicline for smoking cessation provision under PGD, before making any supply under this PGD.
- By signing up to this PGD, the pharmacist accepts personal responsibility for working under it, understands the legal implications of doing so, and works within the scope of the PGD.
- It is the responsibility of the pharmacist to ensure that they have appropriate up to date knowledge of the medicine prior to its supply and to maintain this knowledge and keep up to date with relevant developments, e.g. changes to manufacturer's literature or other changes to guidance that may affect this PGD or the operation of PGDs generally.
- The Provider will be required to comply with GPhC Standards of Conduct, Ethics and Performance and demonstrate maintenance of knowledge, skills and competencies, with evidence of Continuing Professional Development, ideally via CPD entries on to the General Pharmaceutical Council Website [www.uptodate.org.uk/home/welcome.shtml](http://www.uptodate.org.uk/home/welcome.shtml).
- Each pharmacy must have a Standard Operating Procedure in place which covers the supply of varenicline (Champix®) tablets via this PGD.
- Has completed the pre-reading to include: [NCSCT service and delivery guidance](#); varenicline [SPC](#) ; [BMJ systematic review](#) ; [NICE PGD guidance](#) ; [NCSCT varenicline: effectiveness and safety](#) (see also further reading).

### Continued training & competency requirements (applies to all staff)

- Maintenance of own level of updating and competence with evidence of continued professional development.
- The Provider must ensure that supporting pharmacy staff are trained in dealing with patients in a patient-centred, user-friendly, confidential and non-judgmental manner when requesting varenicline. Providers are expected to work towards implementing the Department of Health paper 'You're Welcome' Quality Standards.
- Medicine counter staff must be trained to refer requests for varenicline to the pharmacist, smoking adviser or a suitable alternative provider if a suitably trained member of staff is not present.
- Any continued training requirements as deemed necessary by your organisation or the authorising body (NYCC).

The Supply of

VARENICLINE (CHAMPIX®) TABLETS 0.5MG & 1MG

Individual Healthcare Professional Authorisation

This form can be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named accredited pharmacist.

- This page is to be retained by the individual healthcare professional/practitioner.
This PGD is to be read, agreed to and signed by the registered Healthcare Professional it applies to.
By signing this document, the pharmacist confirms that they understand the PGD, that they are competent to work under this PGD...
Patient Group Directions should be used in conjunction with reference to national or local policies, guidelines or standard text...

Agreement by Pharmacist

I (name of healthcare professional), consider that I am competent to supply varenicline (Champix®) in accordance with this PGD and have completed the Declaration of Competence.

I have read and understood the Patient Group Direction

Varenicline 0.5mg and 1mg Tablets (Champix®) – Direction number: NYCC 2019/CP07

I agree to supply Varenicline 0.5mg and 1mg tablets (Champix®) in accordance with this PGD. I will maintain clinical records as defined by the PGD, PharmOutcomes, SLA & in line with recognised governance standards.

Signature of Healthcare Professional: -

Date signed: GPhC Registration no.:

Full premises address:

Only complete next section if a manager/clinical lead is required to authorise you to use PGDs.

Authorisation from Manager/Clinical Lead to use this PGD:-

I confirm that the pharmacist named above has declared themselves suitably trained & competent to work under this PGD.

I give authorisation on behalf of (INSERT NAME OF ORGANISATION) for the above named pharmacist who has signed the PGD to work under it.

Name of Manager/Clinical Lead: Designation:

Signature of Manager/Clinical Lead: Date signed:

Table with 3 columns: PGD Valid from: 1st July 2019, Review Date: - Dec. 2021, Expiry Date: - 31st July 2021

# Appendix 1 - Assessment to Supply Varenicline Form

## Form 3 – For Pharmacist Use Only - Client Assessment to Supply Varenicline Proforma

Pharmacy Stamp	Client Name:	
	Address:	
	Date of birth:	Tel. number:
	GPs name and address:	
	Average weekly alcohol intake .....	Units / week

(1 Unit = half a pint; 1 unit = 125ml (small glass of wine); 1 unit = single measure of a spirit)

Client questions	Yes	No	Notes
Is the client registered with a GP?			If No - decline treatment & encourage to register
Does the client offer valid consent?			If No - decline treatment
Does the client consent to share information with GP?			If No - decline treatment

**Exclusion Criteria:** Varenicline **cannot** be supplied under PGD if **‘Yes’** applies to any of the following:

Factor	Yes	No	Notes
Is the client sufficiently motivated to quit or use varenicline			If Yes – ask to come back when motivated
Has client had a course of Varenicline in the last 6 months?			If Yes-refer to NYCC. NRT may be considered
Client under 18 years of age			If Yes – consider NRT
Pregnant or breastfeeding women			If Yes – consider NRT
Hypersensitivity to Varenicline or any of its excipients.			If Yes – consider NRT
Does client have a history of, or currently suffers from moderate or severe impaired kidney function or kidney disease?			If Yes – refer to GP
Does client suffer from epilepsy and or has a history of seizures or with other conditions that lower the seizure threshold?			If Yes – refer to GP
Does client have a history of, or currently have unstable cardiovascular (CV) disease or who have had a recent CV event in the past 3 months.			If Yes – refer to GP
Does client have a history of feeling depressed, low in mood or been prescribed medication for low mood, depression or anxiety?			If Yes –refer to GP
Have you ever been diagnosed with an eating disorder?			If Yes –refer to GP
Client with current unstable psychiatric illness such as schizophrenia, bipolar disorder, eating disorder and major depressive disorder?			If Yes –refer to GP
Has the client been admitted to a hospital to seek help regarding the unstable psychiatric illness in the past 6 months and whether their psychotropic medication dose was changed in the past 6 months?			If Yes – refer to GP
Is client currently on another licensed smoking cessation therapy? (These will need to be discontinued before patient can be considered for varenicline).			If ‘yes’ - Decline supply and refer back to the stop smoking advisor for review
Is client on any other medication, herbal products or vitamins?			Please list. Check PGD / BNF/SPC and other information resources for interactions.

Action taken:	
Supply:	
Referral to:	Advice given:
The above information is correct and to the best of my knowledge. I have been counselled on the use of Varenicline and understand the advice given to me by the pharmacist. <b>Client’s signature:</b>  Date:	The action specified was based on the information given to me by the client, which, to the best of my knowledge, is correct  <b>Pharmacist’s signature:</b>  Date:

## Appendix 2 – Example GP Notification Letter of Varenicline (Champix®) Initiation

### Form 4 – For Pharmacist Use Only (to be sent to the patients GP after first consultation):

Notification to General Practitioners of supply of varenicline (Champix®) by an NYCC authorised community pharmacist

**Dear practice / receptionist. Please ensure that the Client's GP receives this message**

Date: Pharmacy Stamp  
GP Name:  
GP Address: Pharmacy Tel. no. or email:  
Client ID no.....

Dear Dr ..... (Client's General Practitioner)

**MEDICATION STARTED: Varenicline 0.5mg daily** (as part of a 0.5mg/1mg treatment initiation pack) and titrating up to a maximum of 1mg twice daily from day 8 of treatment)

**Varenicline will start on** (date.....) and is supplied via PGD by pharmacist.

Client's name:  
Date of birth:  
Address:

I saw the above client at my pharmacy today and I have recommended and supplied them with **Varenicline (Champix)** tablets using the NYCC approved patient group direction (PGD) to help their quit smoking attempt. The client will be taking Varenicline for a maximum of 12 weeks from this pharmacy with weekly intensive behavioural support.

I can confirm that they have met the inclusion criteria for the scheme and:

- They are a dependent smoker and are motivated to quit
- They will receive intensive weekly behavioural support from a suitably qualified stop smoking practitioner
- That a full medical history has been taken and they have no contraindications or risk factors for taking varenicline
- The possible side effects and use of the medication have been explained to the client.

**I would be grateful if you could please add this medicine to the client's medication records at your practice.**

No further action would be required from you, as the client will be receiving all supplies of Varenicline from my pharmacy with weekly intensive behavioural support. If there is information within the patient's medical record, which would mean that varenicline is contraindicated in this patient please inform me at the telephone number above within the next 72hours.

Please do not hesitate to contact me should you require any further information regarding this supply **within 72 hours** from the date associated with this message. Many thanks.

Yours Sincerely,

Pharmacists Signature (pharmacist print name)

**Client declaration:** I agree to the pharmacy passing on this information to my GP in order to ensure that my medical records are up to date.

Client's Signature: Date:

Additional notes (e.g. if Client has successfully quit)

## Appendix 3 – Example letter of recommendation (by stop smoking advisor) for varenicline supply

**Form 5 – For Advisor Use Only** (send this letter when referring clients to the pharmacist for varenicline)

**Letter of recommendation (by stop smoking advisor) for varenicline supply  
PGD accredited pharmacist to do rigorous screen prior to supply of Varenicline**

Client ID no..... Date: .....

Dear Pharmacist,

Client Name..... DOB...../...../.....

GP name/practice.....

Client name:.....has enrolled on a smoking cessation programme and with either a 1 to 1 advisor or group to assist them in their attempt to stop smoking.

To further help them in their attempt they would like to use a pharmacological smoking cessation aid (Varenicline – Champix). A discussion with regard to general health status and current medication has taken place and a varenicline screening questionnaire (attached) has been completed that you may find useful.

If you think it is appropriate for this client based on your assessment to use the indicated smoking cessation medication then we would be grateful if you could supply them with a two-week starter titration pack of varenicline in line with the NYCC Varenicline PGD and also discuss its use with them.

We will provide the patient with ongoing support during their treatment with varenicline and will inform you by letter or email of the clients continued engagement with behavioural support. We will also alert you immediately of any side effects or problems experienced by your patient.

The client has set a quit date for..... If varenicline (Champix®) is to be used, it needs to be used for 12 weeks and started 8-14 days before quitting.

Should you have any queries, please do not hesitate to contact me or the service at the number/email below.

Yours sincerely,

.....  
(Advisor signature)

Advisor name: ..... Tel.no. ....

### Service Address

#### **Living Well SmokeFree**

North Yorkshire County Council Specialist Stop Smoking Service  
White Rose House, Thurston Road, Northallerton, DL6 2NA  
Telephone No. 01609 797272  
Email: stop.smoking@northyorks.gov.uk

## Appendix 4 – Example letter of recommendation for follow up varenicline supplies

**Form 5A – For Advisor Use Only** (to be sent to the pharmacist for subsequent supplies of varenicline):

**Letter of recommendation for follow up varenicline supplies only**

PGD accredited Pharmacist to do rigorous screen prior to supply of varenicline (Photocopies not accepted)

(Service address: Sandpiper House, Kingfisher Place. Brook Street, Selby, YO8 4AL)

Date: .....

Patient Name: .....

Client ID no.....

DOB...../...../.....

Address:

Quit date:

GP name/practice.....

Dear Pharmacist,

Patient name:.....have enrolled on a smoking cessation programme and continues to attend the stop smoking programme on a weekly basis and have confirmed a quit date as detailed above.

To further help them in their attempt they would like to continue to use a pharmacological smoking cessation aid (Varenicline – Champix). A discussion with regard to how the client is getting on with medication has taken place with the advisor. I have noted the patient's current smoking status and any side effects experienced and additional notes will be written below.

If you think it is appropriate to continue for this client to use varenicline then we would be grateful if you would discuss this with the patient & supply varenicline (as recommended below) in-line with NYCC Varenicline PGD.

**Smoking status:** Abstinent for 0 2 4 6 8 10 weeks (please circle)  
**(No more than 12 weeks supply)**

**Advisor Recommendation** (delete as applicable)

- Varenicline 1mg tablets (x 28 tablets) 2 weeks supply OR
- Varenicline 0.5mg tablets (x 28 tablets) 2 weeks supply

Yours sincerely,

Advisor signature.....

Advisor name: ..... Tel.....

**Side effects experienced (if any?)**

**Additional Notes:**



## Appendix 5 - Record of supply form only (Page 1 of 3)

### Form 1 – For Pharmacy Use Only (to be used by the pharmacy to record varenicline supply)

#### Record of supply form only – PGD trained Pharmacist

Note: only supply varenicline if you have followed all the guidance under the PGD

Client ID no.....


Name of Client: ..... DOB: ...../...../.....

GP name/practice: .....


Record for each issue <ul style="list-style-type: none"> <li>Date of consultation</li> <li>Name of Pharmacist</li> <li>Sig of Pharmacist</li> </ul>	Action taken  (Include quantity, strength and dose of varenicline supplied. Client to sign.)
Date: 1 Name: Sig:	SUPPLY: Y / N (25 tablet Starter Pack)  Client Signature:
Date: 2 (between day 10 – 14) Name: Sig:	SUPPLY: Y / N (1mg x 28 tablets continuation pack) OR (0.5mg x 56 tablets continuation pack for low strength due to side effects) – <b>Client verifies they are quit at this point</b>  Client Signature:
Date: 3 (between day 21 – 28) Name: Sig:	SUPPLY: Y / N (1mg x 28 tablets continuation pack) OR (0.5mg x 56 tabs continuation pack for low strength due to side effects)  Client Signature:
Date: 4 (between day 35 – 42) Name: Sig:	SUPPLY: Y / N (1mg x 28 tablets continuation pack) OR (0.5mg x 56 tabs continuation pack for low strength due to side effects)  Client Signature:
Date: 5 (between day 49 – 56) Name: Sig:	SUPPLY: Y / N (1mg x 28 tabs continuation pack) OR (0.5mg x 56 tablets continuation pack for low strength due to side effects)  Client Signature:
Date: 6 (between day 63 – 70) Name: Sig:	SUPPLY: Y / N (1mg x 28 tablets continuation pack) OR (0.5mg x 56 tablets continuation pack for low strength due to side effects)  Client Signature:

## Appendix 5 - Record of supply form only - continued (Page 2 of 3)


### Declaration for 1<sup>st</sup> two week supply of varenicline (Week 1):

<b>Note</b>	Clients that do not have to pay must fill in parts 1 and 3. Those who pay must fill in parts 2 and 3. Clients who are not exempt are required to pay one prescription charge per item, (e.g. maximum two charges per voucher)				
<b>Part 1 - Client Exemption Declaration</b>	Indicate exemption category (using 'X' mark). The client doesn't have to pay because he/she:				
A	<input type="checkbox"/>	is under 16 years of age	G	<input type="checkbox"/>	has a valid War Pension exemption certificate
B	<input type="checkbox"/>	is 16, 17 or 18 and in full-time education	L	<input type="checkbox"/>	is named on a current HC2 charges certificate
C	<input type="checkbox"/>	is 60 years of age or over	H	<input type="checkbox"/>	*gets Income Support or <b>income-related</b> Employment and Support Allowance (ESA)
D	<input type="checkbox"/>	has a valid maternity exemption certificate	K	<input type="checkbox"/>	* gets <b>income-based</b> Jobseeker's Allowance
E	<input type="checkbox"/>	has a valid medical exemption certificate	M	<input type="checkbox"/>	* is entitled to, or named on, on a valid NHS Tax Credit Exemption Certificate
F	<input type="checkbox"/>	has a valid prescription pre-payment certificate	S	<input type="checkbox"/>	* has a partner who gets Pension Credit <b>guarantee</b> credit (PCGC)
*I am included in an award of income-based Jobseeker's Allowance, Income-related ESA, Income Support, Pension Credit Guarantee Credit or Tax Credit. I understand that if it is not, appropriate action may be taken. I confirm proper entitlement to exemption.					
<b>Declaration</b> (for clients who do not have to pay): I declare that the information I have given on this form is correct and complete. <b>Now Sign and fill in Part 3</b>					
<b>Part 2</b>	I have paid	£	<b>Now sign and fill in Part 3</b>		
<b>Part 3</b>	Client signature here: 		Date:	/	/

### Declaration for 2<sup>nd</sup> two week supply of varenicline:

<b>Note</b>	Clients that do not have to pay must fill in parts 1 and 3. Those who pay must fill in parts 2 and 3. Clients who are not exempt are required to pay one prescription charge per item, (e.g. maximum two charges per voucher)				
<b>Part 1 - Client Exemption Declaration</b>	Indicate exemption category (using 'X' mark). The client doesn't have to pay because he/she:				
A	<input type="checkbox"/>	is under 16 years of age	G	<input type="checkbox"/>	has a valid War Pension exemption certificate
B	<input type="checkbox"/>	is 16, 17 or 18 and in full-time education	L	<input type="checkbox"/>	is named on a current HC2 charges certificate
C	<input type="checkbox"/>	is 60 years of age or over	H	<input type="checkbox"/>	*gets Income Support or <b>income-related</b> Employment and Support Allowance (ESA)
D	<input type="checkbox"/>	has a valid maternity exemption certificate	K	<input type="checkbox"/>	* gets <b>income-based</b> Jobseeker's Allowance
E	<input type="checkbox"/>	has a valid medical exemption certificate	M	<input type="checkbox"/>	* is entitled to, or named on, on a valid NHS Tax Credit Exemption Certificate
F	<input type="checkbox"/>	has a valid prescription pre-payment certificate	S	<input type="checkbox"/>	* has a partner who gets Pension Credit <b>guarantee</b> credit (PCGC)
*I am included in an award of income-based Jobseeker's Allowance, Income-related ESA, Income Support, Pension Credit Guarantee Credit or Tax Credit. I understand that if it is not, appropriate action may be taken. I confirm proper entitlement to exemption.					
<b>Declaration</b> (for clients who do not have to pay): I declare that the information I have given on this form is correct and complete. <b>Now Sign and fill in Part 3</b>					
<b>Part 2</b>	I have paid	£	<b>Now sign and fill in Part 3</b>		
<b>Part 3</b>	Client signature here: 		Date:	/	/


### Declaration for 3<sup>rd</sup> two week supply:

<b>Note</b>	Clients that do not have to pay must fill in parts 1 and 3. Those who pay must fill in parts 2 and 3. Clients who are not exempt are required to pay one prescription charge per item, (e.g. maximum two charges per voucher)				
<b>Part 1 - Client Exemption Declaration</b>	Indicate exemption category (using 'X' mark). The client doesn't have to pay because he/she:				
A	<input type="checkbox"/>	is under 16 years of age	G	<input type="checkbox"/>	has a valid War Pension exemption certificate
B	<input type="checkbox"/>	is 16, 17 or 18 and in full-time education	L	<input type="checkbox"/>	is named on a current HC2 charges certificate
C	<input type="checkbox"/>	is 60 years of age or over	H	<input type="checkbox"/>	*gets Income Support or <b>income-related</b> Employment and Support Allowance (ESA)
D	<input type="checkbox"/>	has a valid maternity exemption certificate	K	<input type="checkbox"/>	* gets <b>income-based</b> Jobseeker's Allowance
E	<input type="checkbox"/>	has a valid medical exemption certificate	M	<input type="checkbox"/>	* is entitled to, or named on, on a valid NHS Tax Credit Exemption Certificate
F	<input type="checkbox"/>	has a valid prescription pre-payment certificate	S	<input type="checkbox"/>	* has a partner who gets Pension Credit <b>guarantee</b> credit (PCGC)
*I am included in an award of income-based Jobseeker's Allowance, Income-related ESA, Income Support, Pension Credit Guarantee Credit or Tax Credit. I understand that if it is not, appropriate action may be taken. I confirm proper entitlement to exemption.					
<b>Declaration</b> (for clients who do not have to pay): I declare that the information I have given on this form is correct and complete. <b>Now Sign and fill in Part 3</b>					
<b>Part 2</b>	I have paid	£	<b>Now sign and fill in Part 3</b>		
<b>Part 3</b>	Client signature here: 		Date:	/	/




## Appendix 5 - Record of supply form only - continued (Page 3 of 3)


### Declaration for 4<sup>th</sup> two week supply:

<b>Note</b>	Clients that do not have to pay must fill in parts 1 and 3. Those who pay must fill in parts 2 and 3. Clients who are not exempt are required to pay one prescription charge per item, (e.g. maximum two charges per voucher)		
<b>Part 1 - Client Exemption Declaration</b>	Indicate exemption category (using 'X' mark). The client doesn't have to pay because he/she:		
A <input type="checkbox"/>	is under 16 years of age	G <input type="checkbox"/>	has a valid War Pension exemption certificate
B <input type="checkbox"/>	is 16, 17 or 18 and in full-time education	L <input type="checkbox"/>	is named on a current HC2 charges certificate
C <input type="checkbox"/>	is 60 years of age or over	H <input type="checkbox"/>	*gets Income Support or <b>income-related</b> Employment and Support Allowance (ESA)
D <input type="checkbox"/>	has a valid maternity exemption certificate	K <input type="checkbox"/>	* gets <b>income-based</b> Jobseeker's Allowance
E <input type="checkbox"/>	has a valid medical exemption certificate	M <input type="checkbox"/>	* is entitled to, or named on, on a valid NHS Tax Credit Exemption Certificate
F <input type="checkbox"/>	has a valid prescription pre-payment certificate	S <input type="checkbox"/>	* has a partner who gets Pension Credit <b>guarantee</b> credit (PCGC)
*I am included in an award of income-based Jobseeker's Allowance, Income-related ESA, Income Support, Pension Credit Guarantee Credit or Tax Credit. I understand that if it is not, appropriate action may be taken. I confirm proper entitlement to exemption.			
<b>Declaration</b> (for clients who do not have to pay): I declare that the information I have given on this form is correct and complete. <b>Now Sign and fill in Part 3</b>			
<b>Part 2</b>	I have paid	£	<b>Now sign and fill in Part 3</b>
<b>Part 3</b>	Client signature here: 	Date: / /	

### Declaration for 5<sup>th</sup> two week supply:

<b>Note</b>	Clients that do not have to pay must fill in parts 1 and 3. Those who pay must fill in parts 2 and 3. Clients who are not exempt are required to pay one prescription charge per item, (e.g. maximum two charges per voucher)		
<b>Part 1 - Client Exemption Declaration</b>	Indicate exemption category (using 'X' mark). The client doesn't have to pay because he/she:		
A <input type="checkbox"/>	is under 16 years of age	G <input type="checkbox"/>	has a valid War Pension exemption certificate
B <input type="checkbox"/>	is 16, 17 or 18 and in full-time education	L <input type="checkbox"/>	is named on a current HC2 charges certificate
C <input type="checkbox"/>	is 60 years of age or over	H <input type="checkbox"/>	*gets Income Support or <b>income-related</b> Employment and Support Allowance (ESA)
D <input type="checkbox"/>	has a valid maternity exemption certificate	K <input type="checkbox"/>	* gets <b>income-based</b> Jobseeker's Allowance
E <input type="checkbox"/>	has a valid medical exemption certificate	M <input type="checkbox"/>	* is entitled to, or named on, on a valid NHS Tax Credit Exemption Certificate
F <input type="checkbox"/>	has a valid prescription pre-payment certificate	S <input type="checkbox"/>	* has a partner who gets Pension Credit <b>guarantee</b> credit (PCGC)
*I am included in an award of income-based Jobseeker's Allowance, Income-related ESA, Income Support, Pension Credit Guarantee Credit or Tax Credit. I understand that if it is not, appropriate action may be taken. I confirm proper entitlement to exemption.			
<b>Declaration</b> (for clients who do not have to pay): I declare that the information I have given on this form is correct and complete. <b>Now Sign and fill in Part 3</b>			
<b>Part 2</b>	I have paid	£	<b>Now sign and fill in Part 3</b>
<b>Part 3</b>	Client signature here: 	Date: / /	

### Declaration for 6<sup>th</sup> two week supply:

<b>Note</b>	Clients that do not have to pay must fill in parts 1 and 3. Those who pay must fill in parts 2 and 3. Clients who are not exempt are required to pay one prescription charge per item, (e.g. maximum two charges per voucher)		
<b>Part 1 - Client Exemption Declaration</b>	Indicate exemption category (using 'X' mark). The client doesn't have to pay because he/she:		
A <input type="checkbox"/>	is under 16 years of age	G <input type="checkbox"/>	has a valid War Pension exemption certificate
B <input type="checkbox"/>	is 16, 17 or 18 and in full-time education	L <input type="checkbox"/>	is named on a current HC2 charges certificate
C <input type="checkbox"/>	is 60 years of age or over	H <input type="checkbox"/>	*gets Income Support or <b>income-related</b> Employment and Support Allowance (ESA)
D <input type="checkbox"/>	has a valid maternity exemption certificate	K <input type="checkbox"/>	* gets <b>income-based</b> Jobseeker's Allowance
E <input type="checkbox"/>	has a valid medical exemption certificate	M <input type="checkbox"/>	* is entitled to, or named on, on a valid NHS Tax Credit Exemption Certificate
F <input type="checkbox"/>	has a valid prescription pre-payment certificate	S <input type="checkbox"/>	* has a partner who gets Pension Credit <b>guarantee</b> credit (PCGC)
*I am included in an award of income-based Jobseeker's Allowance, Income-related ESA, Income Support, Pension Credit Guarantee Credit or Tax Credit. I understand that if it is not, appropriate action may be taken. I confirm proper entitlement to exemption.			
<b>Declaration</b> (for clients who do not have to pay): I declare that the information I have given on this form is correct and complete. <b>Now Sign and fill in Part 3</b>			
<b>Part 2</b>	I have paid	£	<b>Now sign and fill in Part 3</b>
<b>Part 3</b>	Client signature here: 	Date: / /	



## Appendix 6 – Further reading for pharmacists

- Gibbons, R.D & Mann, J.J.: Varenicline, Smoking Cessation, and Neuropsychiatric Adverse Events; *Am J Psychiatry*. Dec 20 2012: AiA 1-8.
- Thomas, K.H. et al: Smoking cessation treatment and risk of depression, suicide, and self-harm in the Clinical Practice Research Datalink: prospective cohort study; *BMJ* 2013;347:f5704.
- Foulds, J. et al. Effect of Varenicline on Individual Nicotine Withdrawal Symptoms: A Combined Analysis of Eight Randomized, Placebo-Controlled Trials; *Nicotine & Tobacco Research*, Volume 15, Number 11 (November 2013) 1849–1857.