Gibraltar Health Authority
PATIENT GROUP DIRECTION

Issued Under Part 2 of the Medicines (Prescriptions Only) Regulations, 1987 by the Director of Public Health with the consent of the Minister
for

Varenicline (PGD)

LEGAL STATEMENT			
Protocol Issuer	Director of Public Health Gibraltar Health Authority St. Bernard's Hospital Gibraltar Contact Telephone: +(350) 20079160		
Date effective	10th January 2025		
Date of expiry	10th January 2027		
Staff characteristics	See below (section 1)		
Professional Authorisation		SIGNATURE	DATE
Lead Doctor	Dr Helen Carter Director of Public Health [1]		
In Consultation with		SIGNATURE	DATE
Lead Pharmacist	Ms Melanie Gordon Chief Pharmacist		
Lead Nurse	Ms Sandra Gracia Director of Nursing		
Legal Authorisation		SIGNATURE	DATE
With the consent of Minister	The Honourable Minister for Health MP [2] Arias-Vasquez MP		

[1] A Patient Group Direction issued shall only have effect if it is signed by the Director of Public Health with the consent of the Minister.
[2] See footnote 1.

0 Staff Characteristics

Qualifications and professional registration	GNRB/MRB registered professional, employed by GHA, whom is named in the pertinent appendix to this document (Appendix B)
Initial training	All staff authorised to supply Varenicline under this policy/PDG will be named in this PGD. Also, the Director of Public Health has the authority to grant permission for the use of the PGD to qualified professionals. In addition; staff authorised to supply Varenicline under this Policy/PDG should • be trained to deliver Stop Smoking Services (Recommended training - eLfH PGD elearning programme. This training must comply with the pertinent standards for the training of stop smoking service advisers. • be competent to follow and administer Patient Group Direction - showing a clear understanding of drug administration including side effects and contraindications. Individuals operating under this PGD must be familiar with the product and alert to changes in the Summary of Product Characteristics (SPC).
Competency Assessment	All staff authorised to supply Varenicline under this Policy/PDG are required to attend all refresher/update training as required by GHA Stop Smoking Service.
Ongoing training and Competency	Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required. · Organisational PGD and/or medication training as required by employing Trust/organisation.

1 Clinical Conditions / Indication

Clinical condition or situation to which this PGD applies	Tobacco dependence treatment and reduction of nicotine cravings in individuals who smoke and who are willing to seek treatment for tobacco dependence.
Criteria for inclusion	• Informed consent including consent to share relevant information with the individual's GP Practice (via local systems), where registered. • Individuals aged 18 years or older • Individuals who smoke identified as having a long-term goal of tobacco abstinence • Individuals sufficiently motivated to stop tobacco dependence 7-14 days after starting varenicline. • Individual is willing to continue a course of treatment for (at least) 12 weeks, which includes behavioural support, at agreed intervals from their referring tobacco dependence treatment support service. • Individuals dependent on tobacco motivated to engage in a gradual

	approach to quitting smoking but who are not able to quit abruptly. This cohort should reduce smoking during the first 12 weeks of treatment and quit by the end of that treatment period. They should then continue taking varenicline for an additional 12 weeks, a total of 24 weeks of treatment (extended regimen). • Individual agrees to receive advice and treatment from the registered healthcare professional in line with this PGD
Criteria for exclusion	**Individual** • Consent to treatment refused and/or consent refused to share information with the individual's registered GP Practice • Individuals under 18 years of age • Individuals receiving varenicline and/or tobacco dependence treatment (i.e. cytisinicline (cytisine) or bupropion) from another provider • Individuals who have no intention to stop smoking • Individuals who report they are not sufficiently motivated to stop smoking or who are not willing to continue a course of treatment for (at least) 12 weeks and engage in behavioural support. • Individuals unable to absorb oral medications and/or inability to swallow solid oral dosage formulations (i.e. tablets) **Pharmaceutical** • Known hypersensitivity to varenicline or any of the components within the formulation – see Summary of Product Characteristics • Previous intolerable adverse effects with varenicline use, that were not managed by dose reduction • Previous Stevens-Johnson Syndrome or Erythema Multiforme associated with varenicline use **Medical** • Individuals taking clozapine (individuals taking clozapine may be considered for inclusion by organisations, and so removed from PGD exclusions, only if appropriately robust safety measures can be guaranteed locally allowing: o appropriate communication between healthcare providers (i.e. PGD user, clozapine prescriber/prescribing service) and individual re: smoking status and o appropriate clozapine monitoring and o appropriate clozapine dose adjustments • Known or suspected pregnancy (or pregnancy planned during treatment period) [See NICE NG209 guidance for information on recommended tobacco dependence treatment interventions in pregnant individuals]. • Currently breastfeeding • History of seizures or conditions known to lower the seizure threshold • Known or suspected end stage renal disease (CKD stage 5, eGFR <15mL/min/1.73m2) If there are any doubts about the individual's suitability for varenicline the registered healthcare professional working under this PGD must refer the individual to their GP Practice/appropriate specialist and not initiate or continue treatment under this PGD.

Cautions including any relevant action to be taken	**The health risks of tobacco dependence are widely acknowledged and the likelihood of experiencing risks from using varenicline is expected to be lower compared to the risk of continuing to smoke.** **Cardiovascular symptoms**: Individuals taking varenicline should be instructed to notify their GP Practice of new or worsening cardiovascular symptoms and to seek immediate medical attention if they experience signs and symptoms of myocardial infarction or stroke. **Individuals with current or past history of psychiatric disorders** The health benefits of treatment for tobacco dependence are widely acknowledged and any opportunity to stop smoking should be widely supported. However, treatment for tobacco dependence, with or without pharmacotherapy, has been associated with the short-term exacerbation of underlying psychiatric illness (e.g., depression). Changes in behaviour or thinking, anxiety, psychosis, mood swings, aggressive behaviour, depression, suicidal ideation and behaviour and suicide attempts have been reported in individuals attempting to quit smoking. Individuals should be advised to discontinue varenicline immediately and notify their relevant service provider if they experience serious neuropsychiatric symptoms such as agitation, depressed mood, changes in behaviour or thinking, or seek immediate medical advice if they develop suicidal ideation or suicidal behaviour. **Medication related cautions when an individual stops smoking** Physiological changes resulting from smoking cessation, (with or without treatment with varenicline), may alter the pharmacokinetics or pharmacodynamics of some medicinal products, for which dosage adjustment may be necessary. As ingredients in tobacco smoke induce CYP1A2, smoking cessation may result in an increase of plasma levels of CYP1A2 substrates. Before supplying varenicline, PGD users must first establish (using the information presented below) if there is a potential interaction due to a change in smoking status and inform the individual of this. The individual should be informed to notify the prescriber(s) of the interacting medicine(s) **in advance** of their intention to stop smoking. Additionally, the service providing varenicline (i.e. the PGD user) **must** also inform the prescriber(s) of the interacting medicine(s) of the individual's attempt to stop smoking so that any relevant monitoring and/or dose adjustments can be carried out by the individual/their health care professional. How this is communicated should be clearly laid out in the service contract or locally developed SOP. Where an individual has already stopped smoking (or reduced their tobacco consumption or entered a period of temporary abstinence) prior to presenting for treatment with varenicline, the PGD user should ensure

	that the individual has already discussed the potential effect(s) of this action on their existing medication(s) with the relevant prescriber(s) and detail any actions taken. Where this has not occurred, advise the individual to contact the relevant prescriber(s) (or service(s)) as soon as possible, as monitoring (and follow up with the service) may be required. The PGD user must **ensure** the service provider who prescribes any interacting medicine to any individual supplied with varenicline under this PGD are aware of the individual's intention to stop smoking **AND** that a plan is in place re: monitoring and dose adjustments, if required. If the individual is unwilling to share information between services, varenicline must not be supplied under this PGD and the individual should be referred to an appropriate alternative service provider, as per local arrangements. If it is **not possible to inform** the prescriber(s) of the interacting medicine(s) of the individual's intention to stop smoking **so that any relevant monitoring and/or dosage adjustments can be carried out** by the individual/their health care professional, varenicline **must not be** supplied under this PGD and the individual should be **referred** to an appropriate alternative service provider. If individuals **relapse and start smoking again**, they are **required to notify all healthcare practitioners** involved in their care (so that any appropriate monitoring and/or dose adjustments can be actioned). They must be advised of this responsibility and ensure that this information is communicated. The impact of smoking cessation on the following medicines have been classified as: - Very high risk (risk of death AND dosage adjustments required) see Criteria for exclusion - High risk (narrow therapeutic index drug and potential toxicity OR rapid dosage adjustments required) - Moderate risk (increased risk of adverse effects +/- dosage amendments required). **Other cautions** **Cutaneous reactions**: Individuals reporting hypersensitivity reactions (including angioedema) and/or severe skin reactions (e.g., Stevens Johnson syndrome) should discontinue treatment and contact a healthcare provider immediately. Although rare, these reactions have been identified from post-marketing reports. **Effects on ability to drive**: Varenicline may cause dizziness, somnolence and transient loss of consciousness, and therefore may influence the ability to drive and use machines. Individuals should be advised not to drive, operate complex machinery or engage in other potentially hazardous activities until it is known whether varenicline affects their ability to perform these activities. **Alcohol**: There have been post marketing reports of increased intoxicating effects of alcohol in individuals treated with varenicline. A causal relationship between these events and varenicline use has not been established. Individuals should be advised of possible increased intoxicating effects of alcohol when taking varenicline.

	Side effects on treatment cessation: Up to 3% of individuals report side effects (e.g. increase in irritability, urge to smoke, depression or insomnia) on cessation of varenicline treatment. At the final review appointment, if an individual with a high risk of relapse is experiencing side effects (e.g. irritability because of treatment cessation) refer to their GP Practice or other appropriate specialist for consideration of further/tapering doses.
Action to be taken if the individual is excluded	• Record reasons for exclusion in the appropriate clinical record and any advice given to the individual along with the action taken (e.g. referred to GP Practice) • Signpost individual back to the referring service, another relevant provider, their GP Practice, appropriate specialist, or mental health service as appropriate. • Recommend alternative tobacco dependence interventions if appropriate.
Action to be taken if the individual or carer declines treatment	• Document the reason for why the individual declined and any advice given to the individual along with any action taken (e.g. referred to smoking cessation service). • Any individual who declines treatment should be signposted back to the referring service, another relevant provider, their GP Practice, appropriate specialist or mental health service as appropriate. • Recommend alternative smoking cessation interventions if appropriate
Arrangements for referral for medical advice	Refer to the referring service, another relevant provider, an individual's GP Practice, appropriate specialist or mental health service as appropriate.

2 Treatment

Name, strength & formulation of drug	Varenicline 0.5mg and 1mg tablets
Legal category	Prescription Only Medicine (POM)
Route / method of administration	Orally, swallowed whole with water
Indicate any off-label use (if relevant)	**Temperature variations** Medicines should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions the pharmacist must ensure the medicine remains pharmaceutically stable and appropriate for use if it is to be issued. Where medicines have been assessed by a pharmacist in accordance with national or specific product recommendations/manufacturer advice as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected medicines for use lies with the pharmacist.
Dose and frequency of administration	Individuals should set a quit date for 7 to 14 days after initiation of varenicline treatment. **<u>1) Standard regimen</u>**

	Days 1 to 3: 0.5mg once daily **Days 4 to 7**: 0.5mg twice daily **Days 8 onwards (to complete 12 week course)**: 1mg twice daily† until a total of 12 weeks' treatment has been taken. † ***Intolerance of higher dose (1mg twice daily) of varenicline***: for individuals who cannot tolerate the adverse effects (e.g. nausea) of the higher dose of varenicline, and where this is interfering with the attempt to quit, the dose may be reduced temporarily or permanently to 0.5mg twice daily. This reduction should be agreed with the individual and the PGD user. Dose reductions should be initiated at review points for repeat supply. If there are any concerns the individual should be signposted back to the referring service, another relevant provider, their GP Practice, appropriate specialist or mental health service as appropriate. **2) Extended regimen** For individuals who have successfully stopped smoking at the end of 12 weeks' treatment, an additional course of 12 weeks' treatment can be provided, to help maintain abstinence. **Weeks 13 to 24 (to complete 24 week course)**: 1mg twice daily† until a total of 24 weeks' treatment has been taken. † ***Intolerance of higher dose (1mg twice daily) of varenicline***: For individuals who cannot tolerate the adverse effects (e.g. nausea) of the higher dose of varenicline, and where this is interfering with the attempt to quit, the dose may be reduced temporarily or permanently to 0.5mg twice daily. This reduction should be agreed with the individual and the dose reductions should be initiated at review points for repeat supply. If there are any concerns the individual should be signposted back to the referring service, another relevant provider, their GP Practice, appropriate specialist or mental health service as appropriate. **3) Renal dosage regimens**: **For individuals with known moderate renal impairment (CrCl ≥30mL/min and ≤ 50mL/min):** **Days 1 to 3**: 0.5mg once daily **Days 4 to 7**: 0.5mg twice daily **Days 8 onwards (to complete 12 or 24 week course)**: 1mg twice daily* until a total of 12 or 24 weeks' treatment has been taken. **** Intolerance of higher dose (1mg twice daily) of varenicline in individuals with known moderate renal impairment (CrCl ≥30mL/min and ≤ 50mL/min)***: for individuals who do not tolerate the adverse effects (e.g. nausea) of the higher dose of varenicline, the dose may be reduced temporarily or permanently to 1mg once daily. This reduction should be agreed with the individual and the dose reductions should be initiated at review points for repeat supply. If there are any concerns the individual should be signposted back to the referring service, another relevant provider, their GP Practice, appropriate specialist or mental health service as appropriate.

	For individuals with known severe renal impairment (CrCl < 30mL/min): **Days 1 to 3**: 0.5mg once daily **Days 4 onwards (to complete 12 or 24 week course)**:1mg once daily **<u>Tapering dose</u>** Tapering doses are not permitted under this PGD – if potentially indicated refer to an appropriate prescriber. **<u>Renal function clarification</u>**: The doses given above are for individuals with stable chronic kidney disease and reflect the advice for Creatinine Clearance (CrCl) as detailed in the product SPC. If there is a history of renal failure, supply as per the latest documented CrCl results, if available. However, estimated glomerular filtration rate (eGFR) may be more readily available. If eGFR is the only value available, supply according to eGFR (substituting eGFR for the CrCl figures given above). As CrCl tends to overestimate GFR some individuals may receive a higher varenicline dose as a result so individuals should be advised to promptly report any adverse effects. For further information see BNF prescribing in renal impairment guidance.
Duration of Treatment	1. Maximum of 12 weeks permitted for the standard regimen. 2. Maximum of 24 weeks permitted for the extended regimen.
Quantity to be supplied	1) **<u>Standard regimen (to complete 12 week course):</u>** • **<u>Initiation (Days 1 to 14):</u>** Appropriately labelled initiation pack‡ containing 11 x 0.5mg tablets and 14 x 1mg tablets • **<u>Maintenance (Day 15 onwards):</u>** Appropriately labelled packs of 28 x 1mg tablets can be supplied in instalments to a total of 12 weeks' therapy (i.e. 5 installments of 28 x 1mg tablets). ‡ *If there are issues procuring the initiation packs, appropriately labelled packs containing 11 x 0.5mg tablets and 14 x 1mg tablets may be supplied, noting if supplied other than by a registered pharmacist these must be obtained from a licensed pre-packing unit, as per <u>NICE guidance</u>.* 2) **<u>Extended regimen (to complete 24 week course):</u>** • **<u>Initiation (Days 1 to 14):</u>** Appropriately labelled initiation pack‡ containing 11 x 0.5mg tablets and 14 x 1mg tablets • **<u>Maintenance (Day 15 onwards):</u>** Appropriately labelled packs of 28 x 1mg tablets can be supplied in instalments to a total of 24 weeks' therapy. ‡ *If there are issues procuring the initiation packs, appropriately labelled*

	packs containing 11 x 0.5mg tablets and 14 x 1mg tablets may be supplied, noting if supplied other than by a registered pharmacist these must be obtained from a licensed pre-packing unit, as per NICE guidance. ***For either of the above regimens where higher dose (1mg twice daily) of varenicline are not tolerated and dose reduced to 0.5mg twice daily:*** *Appropriately labelled packs of 28 x 0.5mg tablets can be supplied in installments to a total of either 12 weeks' therapy (standard regimen) or 24 weeks' therapy (extended regimen)* 3) **Renal dosage regimens:** **For individuals with known moderate renal impairment (CrCl ≥30mL/min and ≤ 50mL/min):** • **Initiation (Days 1 to 14):** Appropriately labelled initiation pack‡ containing 11 x 0.5mg tablets and 14 x 1mg tablets • **Maintenance (Day 15 onwards):** Appropriately labelled packs of 28 x 1mg tablets can be supplied in instalments to a total of either 12 weeks' therapy (standard regimen) or 24 weeks' therapy (extended regimen) ‡ *If there are issues procuring the initiation packs, appropriately labelled packs containing 11 x 0.5mg tablets and 14 x 1mg tablets may be supplied, noting if supplied other than by a registered pharmacist these must be obtained from a licensed pre-packing unit, as per NICE guidance.* ***For the above regimen where higher dose (1mg twice daily) of varenicline is not tolerated and dose reduced to 1mg once daily:*** *Appropriately labelled packs of 28 x 1mg tablets can be supplied in installments to a total of either 12 weeks' therapy (standard regimen) (i.e. up to 3 installments of 28 x 1mg tablets) or 24 weeks' therapy (extended regimen) (i.e. up to 6 installments of 28 x 1mg tablets).* **For individuals with severe renal impairment (CrCl < 30mL/min):** • **Initiation (Days 1 to 3):** Appropriately labelled pack containing 3 x 0.5mg tablets • **Maintenance (Day 4 onwards):** Appropriately labelled packs of 28 x 1mg tablets can be supplied in installments to a total of either 12 weeks' therapy (standard regimen) or 24 weeks' therapy (extended regimen). **Tapering dose (for individuals at high risk of relapse and experiencing side effects)**: Supply not permitted under this PGD: refer to GP Practice or other appropriate specialist for consideration of further/tapering doses.

Storage	Stock must be securely stored according to organization medicines policy and in conditions in line with SPC, which is available from the electronic Medicines Compendium website
Drug interactions	**Drug-drug interactions:** Whilst the product SPC states that no clinically significant drug-drug interactions exist with varenicline, all concurrent medications must be checked for interactions in case of updated SPC advice. Where a clinically significant drug interaction is identified the individual should be referred to an appropriate clinician for consideration of suitability. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website **Drug-smoking interactions:** Physiological changes resulting from smoking cessation, with or without treatment with varenicline, may alter the pharmacokinetics or pharmacodynamics of some medicinal products, for which dosage adjustment may be necessary. As smoking induces CYP1A2, smoking cessation may result in an increase of plasma levels of CYP1A2 substrates. Refer to *Cautions* section for specific advice. For further advice see: Considering drug interactions with smoking Managing specific interactions with smoking Individuals should be reviewed at each collection point to ensure that any relevant monitoring has been carried out by the individual/their health care professional noting specifically the detail given in Appendix B.
Identification & management of adverse reactions	A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website and the BNF The following side effects are listed in the product SPC/BNF as **very common/common** with varenicline (but may not reflect all reported side effects): ○ Abnormal appetite (increased or decreased) ○ Abnormal dreams ○ Asthenia ○ Chest discomfort (chest pain) ○ Constipation ○ Cough, nasopharyngitis ○ Diarrhoea ○ Dizziness ○ Drowsiness ○ Dry mouth ○ Dysgeusia ○ Dyspnea ○ Fatigue ○ Gastrointestinal discomfort (abdominal distension, abdominal

	pain, dyspepsia, flatulence) ○ Gastrointestinal disorders (including gastroesophageal reflux disease) ○ Headache ○ Insomnia ○ Joint disorders ○ Muscle complaints (arthralgia, myalgia, back pain) ○ Nausea ○ Oral disorders ○ Pain ○ Skin reactions (rash, pruritus) ○ Sleep disorders ○ Toothache ○ Vomiting ○ Increased body weight Reassure the individual that these side effects occur mainly at the beginning of treatment and often resolve, without intervention. These symptoms may also be the result of tobacco withdrawal symptoms and not treatment with varenicline. In the event of a severe adverse reaction (including cutaneous reactions or exacerbation of known psychiatric illness: See Individuals with current or past history of psychiatric disorders for further information), the individual must be advised to stop treatment immediately and seek urgent medical advice.
Management of and reporting procedure for adverse reactions	Healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme or search for MHRA Yellow Card in the Google Play or Apple App Store and send a copy of the Yellow card to the Director of Public Health. Any adverse reaction to a vaccine should also be documented in the individual's record and the individual's GP should be informed. **INFORM GIBRALTAR DIRECTOR OF PUBLIC HEALTH IMMEDIATELY IF SEVERE ADVERSE REACTION IS SUSPECTED**
Written information to be given to patient or carer	Provide marketing authorization holder's patient information leaflet (PIL) provided with the product. Give any additional information in accordance with the local service specification.
Patient advice / follow up treatment	**Pharmaceutical** • Explain the dose, frequency and method of administration, including how to use the initiation pack. • The individual/carer should be advised to read the PIL. • Inform the individual/carer of possible side effects and their management. • The individual/carer should be advised to seek medical advice in the event of a serious adverse reaction.

	• The tablets should be swallowed whole with water, they can be taken either with or without food. There is some evidence that taking with food reduces the likelihood of nausea. • Individuals should be warned that the medicine may make them sleepy and not to drive or operate machinery/tools if affected. Individuals should exercise caution before driving or using machinery until they are reasonably certain that varenicline does not adversely affect their performance. Occupational risk should be highlighted, as appropriate. **Medical/Psychological** • Individuals taking varenicline, or any other treatment for tobacco dependence, should be advised to discontinue treatment and seek prompt medical advice if they develop agitation, depressed mood, or suicidal thoughts (MHRA/CHM advice) and also to contact the PGD user or the tobacco dependence services. • Advise on actions to be taken by individuals with a history of mild to moderate mental health disorders and if their symptoms worsen i.e., discontinue treatment and report to the GP Practice and PGD user as soon as possible. • Tobacco dependence treatment may lead to a change in blood glucose levels. Individuals with diabetes should be advised to be vigilant for signs of hypo/hyperglycaemia and, where usually monitored, be advised to monitor blood glucose more frequently. • Individuals taking medications detailed within the Cautions section of this PGD should be advised on any required action. • Individual to notify their GP Practice of new or worsening cardiovascular symptoms and to seek immediate medical attention if they experience signs and symptoms of myocardial infarction or stroke. **Individual** • Individuals should set a quit date for 7 to 14 days after initiation of varenicline treatment. • Discuss the major reasons for varenicline failure which are: o Unrealistic expectations; o Lack of preparation for the potential for the tablets to cause nausea; o Insufficient or incorrect use; o Insufficient support from a trained tobacco dependence advisor. • Further information that may support adherence as part of shared decision making: o Varenicline works by acting on the parts of the brain which are affected by nicotine in cigarettes. o Varenicline does not remove all temptation to smoke, but it does make abstinence easier (“it takes the edge off the discomfort”). o Approximately one third of individuals may experience mild nausea around 30 minutes after taking varenicline. This reaction usually diminishes gradually over the first few weeks,

	and most people tolerate it without problems. If this occurs, advise the individual to return for consideration of dosage reduction or if severe, individuals should be referred to their G.P. o Tobacco dependence treatment with or without medication is associated with various symptoms (e.g. irritability, poor sleep etc.). Individuals should be made aware that they may experience any of these side effects and on discontinuation of therapy, but it is not clear whether the effects are linked to therapy or to nicotine withdrawal. o Advise this is a short-term treatment for long-term benefit. o Possible physical changes on stopping smoking, e.g. weight gain and how to manage this. o Outline the expectations of both the individual and the PGD user with reference to the ongoing treatment and future appointments. o Details of next consultation with the PGD user. • Advise individual/carer to return any unused medicines to a pharmacy for disposal: Do not dispose of medicines in the bin, down the sink or toilet.
Records	The following records should be kept for all products supplied under this PGD. Entry should be made on EMIS noting consultation and any consequential supplies. Adequate completion of the pertinent EMIS template will ensure that all pertinent info, as detailed below is captured appropriately. • Name of patient • Address of patient • Date of birth of patient • Name of product supplied • Quantity and dosage of product supplied • Date of supply • Batch number and expiry date • Signature of professional supplying the medication (Not required if entry on EMIS only) • Signature of patient (Only at Initial supply/Agreement. Not required if entry on EMIS only)

Appendices

A. Drug Interactions

B. Names of individuals authorised to supply under this PGD

C. References

Appendix A – Drug/Smoking Interactions

Drug-smoking interactions (see Criteria for exclusion)

VERY HIGH RISK:

Medication	Impact of smoking cessation	Possible adverse effects	Action	When to implement action
Clozapine	Metabolism of clozapine is reduced. Lower doses of clozapine needed.	Risk of significant adverse effects, including death and seizures, in individuals who abruptly stop smoking whilst taking clozapine, without dose adjustments.	Ensure the service provider who prescribes clozapine to any individual supplied with varenicline under this PGD are aware of the individual's intention to stop smoking and that a coordinated care plan is in place for clozapine plasma monitoring and dose adjustments **before** varenicline is supplied. Ensure a coordinated care plan is in place for clozapine plasma monitoring and dose adjustments. A record of this care plan should be retained by the PGD user in the individual's clinical record. Individuals must be counselled of the importance of informing their clozapine prescriber if they re-start smoking (as dose increases may be needed).	Prior to varenicline supply

Useful information:

- MHRA/CHM Drug Safety Update: clozapine and other antipsychotics: monitoring blood concentrations for toxicity
- Managing the risks associated with patients prescribed clozapine

HIGH RISK:

Medication	Impact of smoking cessation	Possible adverse effects	Action	When to implement action
Olanzapine	Metabolism of olanzapine is reduced.	Increased risk of adverse events of olanzapine (e.g. dizziness, sedation, hypotension).	Ensure the service provider who prescribes olanzapine to any individual supplied with varenicline under this PGD are aware of the individual's intention to stop smoking **before** varenicline is	Prior to varenicline supply

			supplied.	
Insulin	May affect insulin resistance and enhance insulin sensitivity.	Increased risk of hypoglycemia.	Individuals on insulin may be supplied with varenicline but must be advised to monitor their blood glucose levels closely and of the symptoms of hypoglycemia. If the PGD user has any doubts around the ability of the individual to monitor their blood glucose levels, varenicline must not be supplied under this PGD and the individual should be referred to an appropriate care provider.	Prior to varenicline supply
Theophylline or aminophylline	Metabolism of theophylline and aminophylline are reduced.	Could cause plasma theophylline levels to rise, possibly to toxic levels if the dose of theophylline/aminophylline is not adjusted.	The PGD user must inform the individual's prescriber of their intention to stop smoking and agree subsequent additional monitoring by the prescriber **before** the individual is supplied with varenicline.	Prior to varenicline supply
Warfarin	Metabolism of warfarin is reduced.	Increased risk of adverse effects of warfarin (i.e. bleeding).	Individuals on warfarin may be supplied with varenicline but must advise the INR clinic of their intention to stop smoking using varenicline. A blood test should be arranged with the clinic as per their instructions. The pharmacist should check the individual's yellow book on every scheduled consultation ensuring that their INR is being checked regularly, and that it is within the individual's normal range. If the individual is unwilling to disclose this information, varenicline must not be supplied under this PGD and the individual should be referred to an appropriate care provider.	Prior to varenicline supply
Erlotinib	Metabolism of erlotinib is reduced.	Rapid dose reduction required upon smoking cessation.	Ensure the service provider who prescribes erlotinib to any individual supplied with varenicline under this PGD are aware of the individual's intention to have tobacco dependence treatment and the dose is adjusted accordingly	Prior to varenicline supply

			before varenicline is supplied.	
Riociguat	Metabolism of riociguat is reduced.	Increased risk of adverse effects of riociguat (e.g. dizziness, headache, nausea, diarrhoea).	Ensure the service provider who prescribes riociguat to any individual supplied with varenicline under this PGD are aware of the individual's intention to stop smoking and the dose is adjusted accordingly **before** varenicline is supplied.	Prior to varenicline supply

MODERATE RISK:

Medication	**Impact of smoking cessation**	**Possible adverse effects**	**Action**	**When to implement action**
Chlorpromazine Flecainide Fluvoxamine Haloperidol Methadone Mexiletine Melatonin Riluzole Ropinirole	Metabolism of medication is reduced	Increased risk of adverse effects (see below for further information)	Individuals taking any of the following medicines should be informed of the increased risk of adverse effects when stopping smoking. Ensure the service provider who prescribes any of these interacting medicines to any individual supplied with varenicline under this PGD are aware of the individual's intention to stop smoking and the dose is adjusted accordingly prior to stopping smoking, (if required).	Prior to varenicline supply

Useful information:

- Managing specific interactions with smoking
- Individual drug Summary of Product Characteristics (SPC): accessible via:
  - Electronic medicines compendium
  - MHRA

Appendix B

Practitioner authorisation sheet

Varenicline 0.5mg and 1mg PGD Valid from 10th January 2025 to 10th January 2027:

Before signing this PGD, check that the document has had the necessary authorisations in section two. Without these, this PGD is not lawfully valid.

Practitioner

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

Appendix C:

Guidance and References

This document authorises and sets out the conditions under which Varenicline can be supplied directly to patients whom are entitled to receive GHA provision of healthcare by named individuals. It is based on relevant guidance issued by UK D of H, NICE etc. It incorporates and is sensitive to local practices which precede this PGD/policy

Key references	• Electronic Medicines Compendium http://www.medicines.org.uk/
	• Electronic BNF https://bnf.nice.org.uk/
	• National Institute for Health and Care Excellence (2013). Overview | Patient group directions | Guidance | NICE | Updated March 2017 Available at: https://www.nice.org.uk/Guidance/MPG2 [
	• National Institute for Health and Care Excellence (2007). Overview | Varenicline for smoking cessation | Guidance | NICE. Available at: https://www.nice.org.uk/guidance/ta123
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