



# **SAMPLE PATIENT GROUP DIRECTION AND SERVICE SPECIFICATION FOR THE SUPPLY OF NICOTINE REPLACEMENT THERAPY THROUGH PHARMACIES**



**ROYAL COLLEGE OF PHYSICIANS**



**The Royal College of General Practitioners is in support of the development of this PGD.**



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*The Pharmacy Healthcare Scheme is a registered charity which aims to develop the contribution of pharmacy to public health through research, training and education.*

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## **GUEST FOREWORD**

Cigarette smoking continues to be the largest single cause of death and disease in England and a major contributor to health inequalities. Stopping smoking is likely to be the most important step a smoker can take to improve their health. Nicotine replacement therapy (NRT) is a highly cost-effective smoking cessation treatment and the Royal College of Physicians (RCP) welcomed the Government's decision to make NRT available on reimbursable NHS prescriptions. NRT is also a very safe treatment and can therefore be prescribed by other health professionals in addition to physicians. This will ensure it is as widely accessible to smokers as possible.

The RCP Tobacco Advisory Group welcomes the development of the Pharmacy Healthcare Scheme's Patient Group Direction / Service Specification for the supply of NRT through pharmacy on the NHS. As well as supporting pharmacists to supply NRT as part of their smoking cessation interventions, it will also enable them to supply to patients receiving support from NHS smoking cessation advisors who cannot prescribe. This will prevent smokers from having to make unnecessary visits to family practitioners to obtain their supplies of NRT.

The PGD will also enable some smokers who currently fall outside the product licence such as young smokers, pregnant smokers and smokers with severe cardiovascular disease to receive NRT on the NHS. Although the evidence base for these smokers is still incomplete, the health risks of continued smoking outweigh the health risks of using NRT which is a considerably safer product than tobacco.

I am sure that local commissioning bodies will find this PGD a useful model for developing local arrangements to supply NRT as part of their programmes to reduce tobacco use in their localities.

**Professor John Britton**  
**Chair, Tobacco Advisory Group of the RCP**

## FOREWORD

I am delighted to introduce this new guidance document from the Pharmacy Healthcare Scheme (PHS). This document is one of a series of PHS publications<sup>1,2</sup> designed to help pharmacists deliver client-centered support and advice on smoking cessation.

The concept of a Patient Group Direction (PGD) will be familiar to most pharmacists and health professionals working at the 'front line' or in health authorities and primary care trusts. They will be aware of its potential to deliver the appropriate medicines to clients conveniently and safely on the NHS.

To facilitate the supply of NRT through pharmacies this document contains a number of sections designed for local adaptation. This includes the Sample PGD itself which, if used, needs to be closely followed to ensure it meets the legal requirements. Further information on the pharmacy supply of products under PGD can be in the Footnotes and from the addresses of pharmacy organisations found towards the very end of the document.

As Chair of the PHS I am aware that much more could be done to develop the contribution of pharmacy to improve the public's health and reduce inequalities. I believe that PHS is ideally placed to help pharmacists do this and that this document is illustrative of the way in which PHS might work to support pharmacy staff put this aim into practice.

I hope this resource will be useful to all those who work in or with pharmacies to deliver NHS smoking cessation services.



**Yve Buckland**  
**Chair of the Pharmacy Healthcare Scheme (PHS)**

June 2001

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<sup>1</sup> Pharmacy Healthcare Scheme. Pharmacists – can you do more to help smokers stop? London: PHS, 2000.

<sup>2</sup> McNeill A and Armstrong M. The impact of amfebutamone (bupropion) on NHS smoking cessation services. *Pharmaceutical Journal* 2000; 265: 860 - 862.

## **SAMPLE PATIENT GROUP DIRECTION (PGD) AND SERVICE SPECIFICATION (SS) FOR THE SUPPLY OF NICOTINE REPLACEMENT THERAPY (NRT) THROUGH PHARMACIES**

*The purpose of this sample PGD and SS is to create a template which NHS commissioning bodies<sup>3</sup> can adapt to meet their own purposes locally. It is intended to provide guidance only as each NHS body is responsible for the information contained in their local PGDs. In particular it is important that only those health professionals who have been given legal authority to supply under PGD will be able to do so<sup>4</sup>.*

### **Introduction**

A PGD is a local mechanism normally set up to allow the supply of Prescription Only Medicines (POMs) on the NHS by health professionals who do not have prescribing rights. Setting up a PGD for NRT is slightly unusual because nicotine is already available on general sale both in medicinal and tobacco products.

NRT became available on NHS prescription from the 17 April 2001 and the Department of Health also announced its intention to phase out the existing national voucher system accordingly. The supply of NRT on prescription has been widely campaigned for by public health groups as NRT is known to double the chances of someone stopping smoking when used correctly<sup>5</sup>. Making NRT available on NHS prescription is expected to increase the number of people using NRT to stop smoking and thereby increase the number of successful quit attempts. It will also increase the number of lower income smokers receiving treatment for smoking which has become increasingly associated with health inequalities.

### **The role of pharmacy in local smoking cessation services**

Recent guidance<sup>6</sup> states that both opportunistic and structured interventions by health professionals are effective in helping people stop smoking. Brief (or opportunistic) interventions carried out by pharmacists or trained members of their staff are important because they can reach a very large number of people – some of whom never or rarely visit their doctor. Guidance on how to carry out brief interventions has been issued to pharmacists by the Pharmacy Healthcare Scheme<sup>7</sup>,

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<sup>3</sup> The term 'NHS commissioning body' is meant to refer to all NHS bodies responsible for commissioning local health services in the UK.

<sup>4</sup> Department of Health. Health Service Circular 2000/026 : Patient Group Directions. DH 2000. Pharmacy technicians and NHS smoking cessation services staff are not allowed to supply unless they have had professional training that allows them to do so, for example, in nursing. Please note this Health Service Circular applies to England only and professionals in Scotland, Wales and Northern Ireland should consult their equivalent guidance.

<sup>5</sup> Raw M, McNeill AD, West R. Smoking cessation guidelines for health professionals. A guide to effective smoking cessation interventions for the health care system. *Thorax* 1998; 53: suppl 5(1): S1-19.

<sup>6</sup> West R, McNeill A, Raw M. Smoking cessation guidelines for health professionals. An update. *Thorax* 2000; 55: 987-9.

<sup>7</sup> Pharmacy Healthcare Scheme. Pharmacists – can you do more to help smokers stop? London: PHS, 2000.

Pharmacists are also effective in helping people stop smoking when trained to provide structured behavioural support<sup>8 9</sup>. Pharmacists providing this level of support (also known as a specialist intervention<sup>10</sup>) have to be approved by an NHS commissioning body and by October 2001 will be expected to meet the relevant standards required by the Department of Health in the NHS Services Monitoring guidance<sup>11</sup>.

Pharmacies also provide a convenient and accessible route to obtain NRT. Both Pharmacy-only and General Sales List products are available for purchase whilst supplies on the NHS can be made by prescription, under PGD or SS, or via the existing voucher system. The existing voucher system allows clients to go directly from the NHS specialist smoking cessation services to a pharmacy to obtain NRT for a short period on the NHS. This supply route will stop when the voucher system is ended but a direct route from the services to the pharmacy can be maintained through a **letter of recommendation to supply** (see Appendix 2). This route allows the client to receive NRT on the NHS without the need to visit the GP surgery to obtain a prescription. The pharmacist can then make the appropriate supply of NRT under PGD after consultation with the client. Normal prescription charges cover the supply of NRT on the NHS via PGD and arrangements will need to be made to allow for this.

## Training

All pharmacists who intend to supply NRT under PGD will need to receive training. Exactly how this is structured and approved will be determined locally but there are a number of key issues to be covered in particular:

- the procedures required to appropriately supply NRT under PGD - including who can supply and when to refer. In particular that the client is only eligible to receive NRT under PGD if they are receiving specialist support. This support might be from the NHS specialist services or from a pharmacist trained to give specialist advice (minimum quality standards for this have been defined<sup>11</sup>)
- the standards required for the completion of any necessary paperwork to claim reimbursement for any NRT supplied on the NHS

Training to supply products under a PGD is normally necessary every two years, however this is only a recommendation and training needs should be reviewed whenever necessary. Ongoing training is available from a number of sources but particularly long-distance learning packs and workshops such as those produced by the national Centres for Pharmacy Postgraduate Education.

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<sup>8</sup> Maguire T A, McElnay J C, Drummond A. A randomised controlled trial of a smoking cessation intervention based in community pharmacies. *Addiction* 2001; 96: 325-331.

<sup>9</sup> Sinclair HK, Bond CM, Lennox AS, et al. Training pharmacists and pharmacy assistants in the stage-of-change model of smoking cessation: a randomised controlled trial in Scotland. *Tobacco Control*, 1998; 7:253-61.

<sup>10</sup> The term 'specialist intervention' includes the category 'intermediate intervention' originally referred to in the Government's Health Circular on the Services. These two categories have recently been combined (see Footnote 9).

<sup>11</sup> Department of Health. NHS Smoking Cessation Services and Monitoring Guidance, DH 2001.

## To PGD or not to PGD for NRT?

A PGD is not normally necessary for pharmacists to supply NRT products that currently are classified as Pharmacy Only (P) or General Sales List (GSL) medicines. So why would it be necessary for a local NHS commissioning body to set up a PGD?

There are two situations where a PGD will be needed:

1. The first is if the manufacturer(s) choose to produce a separate Prescription Only Medicine (POM) licensed NRT product that is significantly cheaper than the current P and GSL products. In this case, local NHS commissioning bodies might not want to fund the supply of the more expensive P or GSL products on the NHS - although these products will continue to be available for purchase. Having NRT available on the NHS from pharmacies will allow clients to access NRT on the NHS *much more easily* (without the need to visit their GP surgery to obtain a prescription) and will *also reach groups who rarely visit a GP*. It is possible that pharmacists may be able to prescribe NRT on the NHS at a later date - but the framework required to do this is not yet in place.
2. The second situation is where the local NHS commissioning body wishes to supply NRT products outside of the terms of their Summary of Product Characteristics (SPCs). Certain NRT products are not licensed for use by particular groups of people, for example, under 18 year olds or pregnant women. These groups are not included under the current licence terms because at the time of their application there was not considered to be enough evidence to guarantee their safe use. However since then there has been widespread professional recognition that using NRT products is much less harmful than continued tobacco smoking and more recently the Commission for the Safety of Medicines has approved the reclassification of certain Pharmacy Only NRT products to become available on general sale<sup>12</sup>. Thus NHS commissioning bodies might want to authorise the supply of NRT outside the licence specifications where continued smoking might cause considerable harm to the smoker or others (for example a developing baby or passive smoking by children). This situation also applies where combinations of NRT products or extended periods of treatment with NRT might be required to help smokers stop.

There are two sample documents to assist the supply of NRT on the NHS through pharmacy in this publication:

- a) the first is a *PGD* covering the supply of P and GSL NRT products *outside* the terms of the SPC. This document could be easily adapted to cover a POM NRT product if one ever became available
- b) the second document is a *service specification* that would allow the supply of P and GSL NRT products on the NHS *within* the terms of the SPC (a PGD is not strictly necessary here)

<sup>12</sup> In recognition of the wider public health interest in making NRT as widely available as tobacco products the Committee on the Safety of Medicines recently recommended that certain NRT products be available on general sale from the 31st May 2001.

**SAMPLE PGD FOR SUPPLYING NRT ON THE NHS<sup>13</sup>**

Name of authorising NHS body	
PGD comes into effect	e.g. 17 04 2001
PGD to be reviewed	e.g. 16 04 2003
Supply and legal classification (P -Pharmacy; G – GSL)	<p>NRT may be supplied in the following forms:</p> <p><b>Gum</b> – 2mg (GSL); 4mg (GSL)</p> <p><b>Patch</b> – 5mg /16 hrs (GSL); 10mg /16 hrs (GSL); 15mg /16 hrs (GSL); 7mg /24 hrs (GSL); 14mg /24hrs (GSL); 21mg /24 hrs (GSL).</p> <p><b>Lozenge</b> – 1mg (GSL)</p> <p><b>Sublingual tablet</b> – 2mg (P)</p> <p><b>Inhalator</b> – 10mg / cartridge (P)</p> <p><b>Nasal spray</b> – 500 micrograms / metered spray (P)</p> <p><b>All supplies:</b> Maximum length of treatment is normally 12 weeks (but check individual product specifications – Appendix 1)<sup>14</sup>.</p>
Class of health professional who may supply NRT	Pharmacists who have received training to supply NRT under this PGD
When supply can be made outside the terms of the SPC?	NRT may be supplied outside the terms of the SPC to <sup>15</sup> :

<sup>13</sup> Based on the template issued by the Royal Pharmaceutical Society of Great Britain (RPSGB) Professional Standards Directorate – Patient Group Directions. A resource pack for pharmacists.

<sup>14</sup> Please note that Appendix 1 is part of both the PGD and the service specification. Strictly speaking any changes made to the product licences, for example, additional products becoming available on general sale, will require a review of the whole PGD accordingly.

<sup>15</sup> There is widespread professional recognition that NRT products are much less harmful than tobacco smoking. Thus NHS commissioning bodies might want to authorise the supply of NRT outside the licence specifications to groups where continued smoking might cause considerable harm to themselves or others, or where combinations of NRT products or extended periods of treatment with NRT might be necessary.

	<ul style="list-style-type: none"> <li>• Clients who are under 18 years old</li> <li>• Clients with <i>severe</i><sup>16</sup> cardiovascular disease (including severe arrhythmias or <i>immediate</i><sup>17</sup> post-myocardial infarction period)</li> <li>• Clients with a history of <i>recent</i><sup>18</sup> cerebrovascular disease (including transient ischaemic attacks)</li> <li>• Pregnant or breastfeeding women</li> </ul> <p>AND / OR when:</p> <ul style="list-style-type: none"> <li>• A combination of NRT products is recommended<sup>19</sup></li> <li>• Continuing supplies are required beyond the specified maximum length of treatment</li> </ul>
<p>Clinical situations for which the medicine is to be used</p>	<p>As an aid to treating tobacco dependence in:</p> <ul style="list-style-type: none"> <li>• Clients receiving specialist advice and support from the NHS smoking cessation services</li> <li>• Clients receiving specialist smoking cessation advice and support from pharmacists</li> </ul>
<p>Criteria for inclusion</p>	<ul style="list-style-type: none"> <li>• Tobacco users identified as sufficiently motivated to quit<sup>20</sup></li> </ul>
<p>Criteria for exclusion</p>	<ul style="list-style-type: none"> <li>• Tobacco users not sufficiently motivated to quit or use NRT</li> </ul>

<sup>16</sup> The precise definition of descriptive clinical terms such as 'severe', 'immediate' and 'recent' will need to be specified locally by the authorising Senior Clinician or other appropriate expert and included in the training programme for pharmacists. The suggested minimum length of time between a severe or recent cardiovascular episode and the patient starting a course of NRT is 2 weeks.

<sup>17</sup> See Footnote 16.

<sup>18</sup> See Footnote 16.

<sup>19</sup> Possible combinations of NRT products include the use of two patches (for very dependent smokers) or the combination of the patch (a slow release form of NRT) with a faster acting NRT such as the gum or nasal nicotine spray with the patch (to allow good control over the nicotine dose during cravings).

<sup>20</sup> The term 'sufficiently motivated to quit' refers to a client's willingness to set a quit date and receive weekly support for the first four weeks of treatment.

	<ul style="list-style-type: none"> <li>• Clients with <i>severe</i><sup>21</sup> cardiovascular disease to whom supply is not permitted under this PGD</li> <li>• Clients with a history of <i>recent</i><sup>22</sup> cerebrovascular disease to whom supply is not permitted under this PGD</li> <li>• Clients with previous serious reaction to NRT or any of the other ingredients contained in the products, e.g. glue in patch</li> <li>• <i>Patches only</i> – clients with chronic generalised skin disease such as psoriasis, chronic dermatitis and urticaria; clients who have had a previous reaction to transdermal patches; occasional smokers</li> <li>• <i>Nasal spray only</i> – clients with chronic nasal disorders such as polyposis, vasomotor rhinitis and perennial rhinitis</li> </ul>
<p>Criteria for referral</p>	<p>When NRT is thought appropriate but supply through pharmacy is not recommended then the client should be referred to a GP. This might include any of the conditions referred to as exclusion criteria above<sup>23</sup> but also:</p> <ul style="list-style-type: none"> <li>• Clients taking theophylline (see Drug interactions below)</li> <li>• Where intervention with bupropion might be more appropriate</li> </ul>
<p>Dosage and method of administration</p>	<p>See Appendix 1 for individual product details</p>

<sup>21</sup> See Footnote 16.

<sup>22</sup> See Footnote 16.

<sup>23</sup> The sample PGD allows for NRT to be supplied outside the SPC for a number of conditions listed in the section headed ‘When supply can be made outside the terms of the SPC’. If there are any changes made to this section and / or the criteria for exclusion or referral then these changes need to be consistent throughout the PGD and related sections adjusted accordingly.

<p>Period of administration</p>	<p>This will be determined by the specialist adviser but will normally follow these guidelines:</p> <p>Weekly supplies to be given up to four weeks with the offer of weekly support. Support may be offered via telephone where appropriate.</p> <p>If the client is successful in stopping smoking after week 4 (preferably with carbon monoxide validation) treatment is to be given for another 4 weeks before revalidation</p> <p>If the smoker is unsuccessful in staying stopped at 4 weeks then discontinue treatment and suggest they make a fresh start when they are ready again</p> <p>If the smoker is successfully stopped at 8 weeks then another 4 weeks supply can be given before revalidation at week 12</p> <p>If the smoker is successful in abstaining at 12 weeks then treatment should normally be gradually withdrawn after this point unless there is a strong likelihood of relapse without continuing treatment</p>
<p>Drug interactions</p>	<p><b>Theophylline</b> - tobacco smoking increases the metabolism of theophylline. Thus stopping smoking may cause theophylline plasma levels to rise. Clients taking theophylline should be supplied with NRT as appropriate but the pharmacist should inform their GP of their attempt to stop smoking. Permission to pass this information to the GP will need to be obtained from the client (see also Informed consent and Appendix 4).</p> <p>Smoking cessation may also cause alterations in the circulating drug levels of the following (but not normally enough to cause therapeutic problems):</p> <ul style="list-style-type: none"> <li>• Insulin</li> <li>• Adrenergic agonists and antagonists</li> </ul>

	<ul style="list-style-type: none"> <li>• Fluvoxamine</li> <li>• Clozapine</li> <li>• Clomipramine</li> <li>• Imipramine</li> <li>• Olanzapine</li> <li>• Flecainide</li> <li>• Tacrine</li> <li>• Pentazocine</li> </ul>
<p>Side effects</p>	<p>These are usually transient but may include the following, some of which are a consequence of stopping smoking:</p> <p>nausea, dizziness, headaches, cold and flu-like symptoms, palpitations, dyspepsia and other gastro-intestinal disturbances, hiccups, insomnia, vivid dreams, myalgia, chest pain, blood pressure changes, anxiety and irritability, somnolence and impaired concentration, dysmenorrhoea.</p> <p>Product-specific side effects are detailed in Appendix 1.</p>
<p>Advice to client</p>	<p>Advice to clients should include <i>specific product advice</i> plus the following general advice on:</p> <ul style="list-style-type: none"> <li>• withdrawal symptoms</li> <li>• possible changes in the body on stopping smoking, e.g. weight gain, and how to manage these</li> <li>• the effects of smoking tobacco whilst using NRT - particularly in vulnerable groups, e.g. pregnant women, clients with cardiovascular disease</li> <li>• written information on products supplied, self-help leaflets and where to obtain more information, in particular NHS Helpline numbers for:  <b>General advice: 0800 169 0 169</b>  <b>Pregnancy: 0800 169 9 169</b></li> <li>• follow-up and obtaining further supplies of NRT</li> </ul>

<p>Informed consent</p>	<p>Client information relating to the supply of NRT under PGD has to be passed to other health service organisations, for example, a client's GP and the NHS smoking cessation services or the local NHS commissioning body, for a variety of purposes such as audit or payment. The client's informed consent must be obtained before information can be passed to their GP (see also Appendix 4).</p>
<p>Details of record keeping</p>	<p>The pharmacist must keep a record of the consultation for at least two years<sup>24</sup>, and the following documents in particular:</p> <ul style="list-style-type: none"><li>• The letter of 'recommendation to supply' (Appendix 2), or a copy, should be kept with the client's record</li><li>• The GP 'fax information' sheet (Appendix 4) to be completed and signed by the pharmacist and sent to the GP</li><li>• Details of the product(s) supplied, invoices and prescription charges collected (Appendix 5) should be recorded as required for audit purposes</li><li>• Audit forms should be completed and returned as required</li></ul>

<sup>24</sup> The Medicines Act (Miscellaneous Provision) 1997 allows client records to be kept electronically.

**DECLARATION by authorising body:**

This PGD has been authorised by: Name: _____ On behalf of NHS Authorising Body	Signature:
Countersigned by: Name: _____ Senior / Lead Clinician	Signature:
Countersigned by: Name: _____ Senior / Lead Pharmacist	Signature:

*Enquiries relating to this PGD should be addressed to:*

**DECLARATION by pharmacist:**

**I have been appropriately trained to understand the criteria listed above and the administration required to supply NRT in accordance with this PGD.**

Name of pharmacist:

Business address or pharmacy stamp:

RPSGB registration number:

Pharmacist's signature:

Date of signature:

Review date:

**SERVICE SPECIFICATION FOR THE  
SUPPLY OF NRT THROUGH PHARMACY**

Name of authorising NHS body	
Service specification comes into effect	e.g. 17 04 2001
Service specification to be reviewed	e.g. 16 04 2003
Supply and legal classification (P -Pharmacy; G – GSL)	<p>NRT may be supplied in the following forms:</p> <p><b>Gum</b> – 2mg (GSL); 4mg (GSL)</p> <p><b>Patch</b> – 5mg /16 hrs (GSL); 10mg /16 hrs (GSL); 15mg /16 hrs (GSL); 7mg /24 hrs (GSL); 14mg /24hrs (GSL); 21mg /24 hrs (GSL).</p> <p><b>Lozenge</b> – 1mg (GSL)</p> <p><b>Sublingual tablet</b> – 2mg (P)</p> <p><b>Inhalator</b> – 10mg / cartridge (P)</p> <p><b>Nasal spray</b> – 500 micrograms / metered spray (P)</p> <p><b>All supplies:</b> Maximum length of treatment is normally 12 weeks (but check individual product specifications – Appendix 1)<sup>25</sup>.</p>
Class of health professional who may supply NRT	Pharmacists who have received training to supply NRT under this service specification
Clinical situations for which the medicine is to be used	<p>As an aid to treating tobacco dependence in:</p> <ul style="list-style-type: none"> <li>• Clients receiving specialist advice and support from the NHS smoking cessation services</li> </ul> <p>Clients receiving specialist smoking cessation advice and support from pharmacists</p>

<sup>25</sup> See Footnote 14.

<p>Criteria for inclusion</p>	<ul style="list-style-type: none"> <li>• Tobacco users identified as sufficiently motivated to quit<sup>26</sup></li> </ul>
<p>Criteria for exclusion</p>	<ul style="list-style-type: none"> <li>• Tobacco users not sufficiently motivated to quit or use NRT</li> <li>• Pregnant or breastfeeding women</li> <li>• Clients under the age of 18 years</li> <li>• Clients with a <i>recent</i><sup>27</sup> history of cerebrovascular accidents including transient ischaemic attacks</li> <li>• Clients with <i>severe</i><sup>28</sup> cardiovascular disease including severe arrhythmias or <i>immediate</i><sup>29</sup> post-myocardial infarction period</li> <li>• Clients with previous serious reaction to NRT or any of the other ingredients contained in the products, e.g. glue in patch</li> <li>• <i>Patches only</i> – clients with chronic generalised skin disease such as psoriasis, chronic dermatitis and urticaria; clients who have had a previous reaction to transdermal patches; occasional smokers</li> <li>• <i>Nasal spray only</i> – clients with chronic nasal disorders such as polyposis, vasomotor rhinitis and perennial rhinitis</li> </ul>
<p>Criteria for referral</p>	<p>When NRT is thought appropriate but supply through pharmacy on the NHS is not authorised then the client should be referred to a GP (see also 'Criteria for exclusion' above).</p> <p>Clients to be referred include:</p> <ul style="list-style-type: none"> <li>• Smokers under the age of 18 years</li> </ul>

<sup>26</sup> See Footnote 20.

<sup>27</sup> See Footnote 16.

<sup>28</sup> See Footnote 16.

<sup>29</sup> See Footnote 16.

	<ul style="list-style-type: none"> <li>• Pregnant or breastfeeding women</li> <li>• Clients with a recent history of cerebrovascular accidents including transient ischaemic attacks</li> <li>• Clients with severe cardiovascular disease including severe arrhythmias or immediate post-myocardial infarction period</li> </ul> <p>But ALSO:</p> <ul style="list-style-type: none"> <li>• Clients taking theophylline (see Drug interactions below)</li> <li>• Where intervention with bupropion might be more appropriate</li> </ul>
<p>Dosage and method of administration</p>	<p>See Appendix 1 for individual product details</p>
<p>Period of administration</p>	<p>This will be determined by the specialist adviser but will normally follow these guidelines:</p> <p>Weekly supplies to be given up to four weeks with the offer of weekly support. Support may be offered via telephone where appropriate.</p> <p>If the client is successful in stopping smoking after week 4 (preferably with carbon monoxide validation) treatment is to be given for another 4 weeks before revalidation</p> <p>If the smoker is unsuccessful in staying stopped at 4 weeks then discontinue treatment and suggest they make a fresh start when they are ready again</p> <p>If the smoker is successfully stopped at 8 weeks then another 4 weeks supply can be given before revalidation at week 12</p> <p>If the smoker is successful in abstaining at 12 weeks then treatment should normally be gradually withdrawn after</p>

	<p>this point unless there is a strong likelihood of relapse without continuing treatment</p>
<p>Drug interactions</p>	<p><b>Theophylline</b> - tobacco smoking increases the metabolism of theophylline. Thus stopping smoking may cause theophylline plasma levels to rise. Clients taking theophylline should be supplied with NRT as appropriate but the pharmacist should inform their GP of their attempt to stop smoking. Permission to pass this information to the GP will need to be obtained from the client (see also Informed consent and Appendix 4).</p> <p>Smoking cessation may also cause alterations in the circulating drug levels of the following (but not normally enough to cause therapeutic problems):</p> <ul style="list-style-type: none"> <li>• Insulin</li> <li>• Adrenergic agonists and antagonists</li> <li>• Fluvoxamine</li> <li>• Clozapine</li> <li>• Clomipramine</li> <li>• Imipramine</li> <li>• Olanzapine</li> <li>• Flecainide</li> <li>• Tacrine</li> <li>• Pentazocine</li> </ul>
<p>Side effects</p>	<p>These are usually transient but may include the following, some of which are a consequence of stopping smoking:</p> <p>nausea, dizziness, headaches, cold and flu-like symptoms, palpitations, dyspepsia and other gastro-intestinal disturbances, hiccups, insomnia, vivid dreams, myalgia, chest pain, blood pressure changes, anxiety and irritability, somnolence and impaired concentration, dysmenorrhoea.</p> <p>Product-specific side effects are detailed in Appendix 1.</p>
<p>Advice to clients</p>	<p>Advice to clients should include <i>specific</i></p>

	<p><i>product advice</i> plus the following general advice on:</p> <ul style="list-style-type: none"> <li>• withdrawal symptoms</li> <li>• possible changes in the body on stopping smoking, e.g. weight gain, and how to manage these</li> <li>• the effects of smoking tobacco whilst using NRT - particularly in vulnerable groups, e.g. pregnant women, clients with cardiovascular disease</li> <li>• written information on products supplied, self-help leaflets and where to obtain more information, in particular NHS Helpline numbers for:  <b>General advice: 0800 169 0 169</b>  <b>Pregnancy: 0800 169 9 169</b></li> <li>• follow-up and obtaining further supplies of NRT</li> </ul>
<p>Informed consent</p>	<p>Client information relating to the supply of NRT under PGD has to be passed to other health service organisations, for example, a client's GP and the NHS smoking cessation services or the local NHS commissioning body, for a variety of purposes such as audit or payment. The client's informed consent must be obtained before information can be passed to their GP (see also Appendix 4).</p>

**Additional notes for service specification:**

Please note that a service specification does not have the same legal requirements as a PGD and therefore does not necessarily require the same level of detail to be recorded. It is for local NHS commissioning bodies to determine if or how they intend to formalise the supply of NRT on the NHS *within the SPC* through pharmacy.

**Appendix 1 – Dosage and method of administration of NRT products**

A) GUM

<p>Dose and method of administration</p>	<p>Oral administration (as resin).</p> <p><i>Nicotinell – 2mg gum</i> For individuals smoking 20 cigarettes or less daily – one 2mg piece chewed slowly for 30 minutes on urge to smoke.</p> <p><i>Nicorette – 2mg gum</i> For individuals smoking 20 cigarettes or less daily – one 2mg piece chewed slowly for 30 minutes on urge to smoke.</p> <p>Individuals needing more than 15 pieces of 2mg gum a day should consider the 4mg gum instead.</p> <p><i>Nicorette – 4mg gum</i> For individuals smoking more than 20 cigarettes a day – one 4mg piece chewed slowly for 30 minutes on urge to smoke.</p> <p><i>Nicotinell – 4mg gum</i> For individuals smoking more than 20 cigarettes a day – one 4mg piece chewed slowly for 30 minutes on urge to smoke.</p> <p>Maximum number of pieces a day: 15 pieces of 4mg gum.</p> <p>Treatment should be continued for at least 3 months followed by a gradual reduction in dosage.</p>
<p>Specific side effects</p>	<p>Throat irritation, increased salivation, hiccups.</p>
<p>Specific advice to client</p>	<p>Gum should be chewed until the taste becomes strong and then ‘parked’ between the gum and cheek until the taste fades. Recommence chewing once the taste has faded. This ‘chew-rest-chew’ technique should be applied for 30 minutes.</p>

B) INHALATOR

Dose and method of administration	<p>Oral administration (nicotine-impregnated plug in mouthpiece).</p> <p>Inhale when urge to smoke occurs.          Advise using 6-12 cartridges (10mg / cartridge) daily for up to 8 weeks THEN          Reducing the dose to 3 – 6 cartridges over the next 2 weeks THEN          Reduce to 0 over next 2 weeks.</p> <p>Review treatment if abstinence not achieved in 3 months.</p>
Specific side effects	<p>Throat irritation, cough, rhinitis, pharyngitis, stomatitis, dry mouth.</p>
Specific advice to client	<p>Air should be drawn into the mouth through the mouthpiece. Clients should be warned that the inhalator requires more effort to inhale than a cigarette and that less nicotine is delivered per inhalation. Therefore the client may need to inhale for longer than with a cigarette.</p> <p>The inhalator is best used at room temperatures as nicotine delivery is affected by temperature.</p> <p>Used cartridges will contain residual nicotine and should be disposed of safely. Advise the client to keep them in the case and dispose of them in household rubbish.</p>

C) LOZENGE

Dose and method of administration	<p>Oral administration (nicotine as bitartrate).</p> <p>Initially one lozenge (1mg) every 1-2 hours on urge to smoke.          Maximum dosage: 25 lozenges per day.</p> <p>Withdraw treatment gradually after 3 months.          Maximum period of treatment: 6 months</p>
Specific side effects	<p>Throat irritation, increased salivation, hiccups.</p>
Specific advice to client	<p>Lozenge should be sucked until the taste is strong and then ‘parked’ between the gum and the cheek until the taste fades. Once faded then sucking should recommence.</p> <p>Simultaneous use of coffee, acid drinks and soft drinks may decrease absorption of nicotine and should be avoided for 15 minutes prior to sucking lozenge.</p>

D) NASAL SPRAY

Dose and method of administration	Nasal administration (500 micrograms / metered spray).  Apply one spray into each nostril as required up to a maximum of twice per hour, over a 16 hour period (= maximum of 64 sprays daily) for a period of 8 weeks THEN Reduce dosage gradually over next 4 weeks achieving half the dose reduction required in the first 2 weeks THEN Continue to reduce dosage to 0 over next 2 weeks.  Maximum period of treatment: 3 months
Specific side effects	Nose and throat irritation, nosebleeds, watering eyes, ear sensations.
Specific advice to client	Advise on correct use of spray. Warn of possible local effects but also that these tend to lessen within a few days. CAUTION – the nasal spray should not be used whilst driving or operating machinery as local effects can predispose to an accident.

## E) PATCHES

Dose and method of administration	<p>Transdermal administration.</p> <p>Apply on waking to dry, non-hairy skin on hip, chest or upper arm. Remove after time specified. New patch should be placed on a different area – avoiding ‘used’ sites for several days afterwards. If successful then gradually reduce dosage with time but review treatment if individual has not stopped smoking at 12 weeks.</p> <p><i>Nicorette – 16 hour patch</i>  15mg patch for 16 hours daily for 8 weeks THEN  10mg “ “ “ “ “ “ 2 “ THEN  5mg “ “ “ “ “ “ 2 “ THEN review treatment</p> <p><i>Nicotinell - TTS30 patch</i>  For individuals smoking more than 20 cigarettes per day – one patch (21mg) daily.</p> <p><i>Nicotinell – TTS20 patch</i>  For individuals smoking 20 cigarettes or less per day – one patch (14mg) daily.</p> <p><i>Nicotinell – TTS10 patch</i>  For individuals smoking 10 cigarettes or less per day – one patch (7mg) daily. It is recommended that smokers begin treatment with one of the stronger patches.</p> <p>Withdraw treatment gradually reducing the dose every 3-4 weeks.</p> <p><i>NiQuitin CQ</i>  For individuals smoking 10 or more cigarettes daily:  21mg patch daily for 6 weeks THEN  14mg “ “ “ 2 “ THEN  7mg “ “ “ 2 “ THEN review treatment</p> <p>Individuals who experience persistent side effects with the 21mg patch should switch to the 14mg for the remainder of the 6 weeks followed by the 7mg patch for 2 weeks as above.</p> <p><i>NiQuitin CQ</i>  For individuals smoking less than 10 cigarettes per day:  14mg patch daily for 6 weeks THEN  7mg “ “ “ 2 “ THEN review treatment</p> <p><b><i>Other brands to be listed as necessary.</i></b></p>
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Specific side effects	Skin reactions. Discontinue use if severe.
Specific advice to client	<p>Exercise may increase absorption of nicotine and therefore side effects.</p> <p>The patch should be applied once a day, normally in the morning, to a clean, dry, non-hairy area of skin on the hip, trunk or upper arm. Allow several days before replacing the patch on a previously 'used' area. Place the patch in the palm of the hand and hold onto the skin for 10-20 seconds.</p> <p>Patches should not be applied to broken or inflamed skin.</p> <p>Once the patch is spent it should be folded in half and disposed of carefully.</p> <p>Clients should not try to alter the dose of the patch by cutting it up.</p>

#### F) SUBLINGUAL TABLET

Dose and method of administration	<p>Oral administration (sublingual) – 2mg.</p> <p>For individuals smoking 20 cigarettes or less daily – 2mg per hour.</p> <p>For patients who fail to stop smoking or have significant withdrawal symptoms consider increasing to 4mg per hour sublingually.</p> <p>For individuals smoking more than 20 cigarettes a day – 4mg per hour.</p> <p>Maximum dose: 80mg per day</p> <p>Treatment should be continued for at least 3 months up to a maximum of 6 months. Dosage should be gradually reduced after 3 months.</p>
Specific side effects	Throat irritation, unpleasant taste.
Specific advice to client	Tablets should be placed under the tongue and allowed to dissolve slowly.

**Appendix 2 – Letter of recommendation to supply NRT**

LETTER OF RECOMMENDATION TO SUPPLY NRT

Dear Pharmacist,

I have discussed NRT treatment with this patient at our clinic today and I should be grateful if you would consider supplying the following NRT products:

Client Name: .....

Client Number: .....(for audit purposes)

Address: .....

.....

<u>NRT Products</u>	<u>Product Code</u>
NICOTINE PATCH 15mg/16 hours	01
NICOTINE PATCH 10mg/16 hours	02
NICOTINE PATCH 5mg/16 hours	03
NICOTINE PATCH 21mg/24 hours	04
NICOTINE PATCH 14mg/24 hours	05
NICOTINE PATCH 7mg/24 hours	06
NICOTINE GUM 4mg	07
NICOTINE GUM 2mg	08
NICOTINE NASAL SPRAY	09
NICOTINE SUBLINGUAL TABLET	10
NICOTINE LOZENGE 1mg	11
NICOTINE INHALATOR	12

**Recommendation**

	Product		Week(s) Supply	
1.				Name: _____
2.				Signature: _____
				Date: _____

*Please delete recommendation 2. if a second product is not required.*

Example: To give one weeks supply of the inhalator:

Product		Week(s) Supply
1	2	1

**Appendix 3 – Names of individuals permitted to supply under the PGD**

***TO BE COMPLETED LOCALLY AFTER TRAINING***

NAME OF PHARMACIST	PHARMACY ADDRESS OR ADDRESSES	CONTACT DETAILS	DATE TRAINING COMPLETED

**Appendix 4 – Notification of supply of NRT to GP and, if appropriate, the NHS smoking cessation services**

**URGENT & CONFIDENTIAL FAX**

**Data protection confidentiality note: This message is intended only for the use of the individual or entity to whom it is addressed and may contain information that is privileged, confidential & exempt from disclosure under law. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited.**

GP Name \_\_\_\_\_  
GP Address \_\_\_\_\_  
\_\_\_\_\_

**Notification of client supply of NICOTINE REPLACEMENT THERAPY**

Pharmacy stamp

Client's name \_\_\_\_\_  
Address \_\_\_\_\_  
\_\_\_\_\_  
DOB \_\_\_\_\_  
Telephone \_\_\_\_\_

**Quit date set:**

**Product(s) supplied:**

**Dose and length of treatment:**

**Total number of weeks supply of NRT given since quit date:**

**Specific advice given:**

**Is the client taking theophylline?**      NO                      YES\*

\* If YES, then the client may need their plasma theophylline levels checked as stopping smoking decreases the metabolism of theophylline.

**Client is receiving follow up from:**    Pharmacy above      NHS smoking cessation services

**Client declaration:** I agree to the pharmacy passing on this information to my GP and the NHS smoking cessation services if necessary

Client signature \_\_\_\_\_ Date: \_\_\_\_\_

## **Appendix 5 – Patient declaration for prescription charges**

To be completed by all clients receiving NRT products through the PGD scheme.  
Clients not exempt from prescription charges require a charge of £6.10 *per item*.

*[Photocopy the back of an FP10 C form here for the client to complete]*

## **MORE INFORMATION**

### **Further information on pharmacy supply under PGD can be obtained from:**

Professional Standards Directorate  
Royal Pharmaceutical Society of Great Britain  
1 Lambeth High Street  
London SE1 7JN  
Tel: 020 7735 9141

National Pharmaceutical Association  
Mallinson House  
38 - 42 St Peter's Street  
St Albans  
Herts AL1 3NP  
Tel: 01727 832 161

PSNC  
59 Buckingham Street  
Aylesbury  
Bucks HP20 2PJ  
Tel: 01296 432823

### **Further details on the NHS Smoking Cessation Services can be obtained from:**

Department of Health  
[www.doh.gov.uk](http://www.doh.gov.uk)

ASH  
[www.ash.org.uk](http://www.ash.org.uk)

<http://www.ash.org.uk/?cessation> - this brings up the full cessation menu

For the document Smoking cessation services; implementing the NHS National Plan go to:

<http://www.ash.org.uk/html/cessation/impnatplan.html>

and

<http://www.ash.org.uk/html/cessation/impnatplan.pdf>