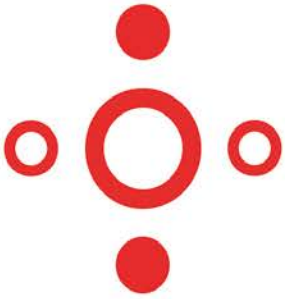
Grŵp Strategaeth Meddyginiaethau Cymru Gyfan
All Wales Medicines Strategy Group



Shared Care Prescribing and Monitoring Guidance

February 2021

This document has been prepared by the All Wales Prescribing Advisory Group (AWPAG) with support from the All Wales Therapeutics and Toxicology Centre (AWTTC, and has subsequently been endorsed by the All Wales Medicines Strategy Group (AWMSG).

Please direct any queries to AWTTC:

All Wales Therapeutics and Toxicology Centre
The Routledge Academic Centre
University Hospital Llandough
Penlan Road
Llandough
Vale of Glamorgan
CF64 2XX

awttc@wales.nhs.uk
029 218 26900

CONTENTS

GLOSSARY

DES - Directed Enhanced Service
All health boards must commission or provide.

LES - Local Enhanced Service
Optional commissioning of services based on local needs.

NES - National Enhanced Service
All health boards advised to commission or provide but not mandatory.

Specialist
Consultant, suitably trained non-medical prescriber, or GP with a specialist interest within a secondary, tertiary, or primary care clinic.

Primary care prescriber
GP or non-medical prescriber.

Unlicensed medicine
Medicines that are used outside the terms of their UK licence or which have no licence for use in the UK[1].

Off label use
Use of a medicine for an unapproved indication or in an unapproved age group, dosage, or route of administration[2].

1.0 BACKGROUND AND DEFINITIONS

A definition of shared care was developed by the All Wales Medicines Strategy Group (AWMSG) in 2006[3]:

> "A simple definition of shared-care would be where a GP supports and prescribes treatment for a patient which was initiated by a specialist. Implicit in a shared care arrangement is that the patient continues to be followed-up in reviews by the specialist. There should be a clear plan of care and defined protocol, with a statement of monitoring arrangements, and responsibilities of the specialist, GP and patient. In order for this to be workable GPs should be able to decide not to share-care because they do not feel they can accept responsibility, or they feel insufficiently competent, on an individual case basis (i.e. in complex cases)."

In 2018, the NHS England Primary Care Delivery: Policy & Strategy, Operations & Information Directorate in partnership with BMA, RCGP, RCN and NAPP issued guidance entitled Responsibility for prescribing between Primary & Secondary/Tertiary Care[4]. This defined shared care as:

> "Shared care agreements are a specific approach to the seamless prescribing and monitoring of medicines which enables patients to receive care in an integrated and convenient manner. Shared care is a particular form of the transfer of clinical responsibility from a hospital or specialist service to general practice in which prescribing by the GP, or other primary care prescriber, is supported by a shared care agreement."

In practice within NHS Wales, for medicines, the term shared care has come to represent circumstances where primary care accept transfer of prescribing responsibility from specialist care, for medicines that have long-term regular monitoring requirements particularly in relation to potential adverse effects. The monitoring arrangements and responsibilities are set out within a formal shared care protocol for the specific treatment, and the patient continues to be followed-up in reviews by the specialist.

Some drug treatments are also covered by a DES, NES or LES for initiation or continued prescribing and monitoring of a drug by primary care outside of a formal shared care agreement. Although these may be accompanied service specifications they do not constitute a formal shared care protocol and are outside the scope of this document.

Near patient testing also covers the situation where a specialist initiates treatment, or recommends initiation of treatment but may not be involved in subsequent follow-up. The responsibility for monitoring treatment then lies with the practice, and in most cases, the primary care prescriber accepts responsibility for continuing drug therapy, and legal responsibility for prescribing[3]. Near patient testing is outside the scope of this document.

Increasingly, health boards have provided additional written support documents to facilitate safe and effective transfer of prescribing responsibility between specialist care and primary care. These do not entail significant ongoing monitoring requirements and do not involve separate remuneration for ongoing prescribing by primary care. It is important to recognise that this does not constitute formal shared care and is outside the scope of this document.

Health boards have policies in place for the transfer of prescribing responsibility between secondary and primary care. These are based on good practice guidance from the GMC[5], principles and best practice for shared care protocols should be viewed in the broader context of these policies.

Good organisation of care across the interface between primary and secondary/tertiary care is crucial in ensuring that patients receive high quality care – and in making the best use of clinical time and NHS resources in all care. Lack of communication between primary and secondary/tertiary care and misunderstandings around the responsibilities of the professionals involved are often cited as reasons for patients not being able to get their medicines in a timely manner, despite effective collaborative working and communication being an important part of patient-centred professionalism[4]. Communication between primary and secondary care should take into account the advice contained in the All Wales Communication Standards between Primary and Secondary Care.

Within NHS Wales there are now a considerable number of non-medical prescribers, this resource should be considered in the context of shared care. This prescribing guidance applies to these professional groups within both the primary and secondary care setting.

2.0 BEST PRACTICE AND PRINCIPLES FOR SHARED CARE

2.1 National shared care protocols should be considered for local adoption where available. If a national shared care protocol is not available it is recommended that shared care arrangements should be drawn up following local discussion and agreement by prescribing parties and should outline the respective clinical responsibilities of all parties.

2.2 Each health board will maintain a list of shared care protocols which are available within their local formularies along with details of any associated enhanced services.

2.3 Shared care protocols should only be endorsed where the safety profile of the medicine is such that regular ongoing monitoring is required. In some circumstances, the treatment may need regular ongoing monitoring for efficacy and adverse drug reactions, where this can be provided within primary care a shared care protocol may be considered. Regular in this context is a minimum frequency of 6 monthly.

2.4 Shared care may be initiated by or at the recommendation of a specialist. Sharing of clinical responsibility with primary care should only be considered where a patient's clinical condition is stable, predictable and their treatment has been initiated and stabilised in, or by the specialist setting for a minimum of 4 - 6 weeks. At this point, the specialist may seek the agreement of the primary care prescriber concerned (and the patient) to participate in a formal shared care agreement.

2.5 In proposing a shared care agreement, the specialist should advise which medicine to prescribe, what monitoring will need to take place in primary care, how often the medicine must be reviewed, and what action to take in the event of difficulties. This must be captured in a formal written shared care protocol and should include a route of return to specialist care if the condition changes and requires specialist clinical review. (See Appendix 1 – template Shared Care Agreement form and Shared Care Protocol)

2.6 The primary care prescriber should confirm the agreement and acceptance of the shared care prescribing arrangement within a locally agreed timeframe, and confirm that supply arrangements have been finalised (See Appendix 2 – template letter Primary Care Response).

2.7 Sharing of prescribing and monitoring with the primary care prescriber should only take place once the primary care prescriber has agreed to this in each individual case. The specialist provider must supply an adequate amount of the medicine to cover the transition period. Where there is no agreement in respect of arrangements for prescribing, responsibility for prescribing remains with the specialist until resolved. Transfer of prescribing responsibility to a primary care prescriber without prior agreement is not appropriate.

2.8 The primary care prescriber is under no obligation to accept transfer of prescribing responsibility, this includes participation in health board approved shared care agreements. The decision to accept transfer of prescribing responsibility should be taken on an individual patient basis by the individual practitioner. In cases where a GP practice usually participates in a particular shared care agreement, the reason for declination of participation in shared care for a specific patient should be communicated to the specialist. Refusal by a primary care prescriber to share care and prescribing responsibilities should not prevent a clinically appropriate therapy being prescribed by a specialist (See Appendix 2 – template letter Primary Care Response).

2.9 As for all transfer of prescribing responsibility, transfer involving a shared care agreement should be seamless to ensure the patient receives care in an integrated and convenient manner. Patients should never be placed in a position where they are unable to obtain their medicines because of a lack of communication between primary and specialist care.

2.10 Where a patient under a shared care agreement transfers GP practice, the primary care prescriber should liaise with the initiating specialist and, if appropriate, former GP practice. Local arrangements may exist to facilitate this.

2.11 The need and duration of stabilisation will vary between treatments, however, the specific details should be detailed within each shared care protocol following specialist initiation. The shared care protocol should be comprehensive and clearly define the areas of care for which each partner is responsible. Prescribers are responsible for developing their knowledge and skills to be able to safely prescribe.

2.12 Clinical responsibility for prescribing should sit with those professionals who are in the best position and appropriately skilled to deliver care which meets the needs of the patient. When clinical responsibility for prescribing is transferred to general practice, it is important that the primary care prescriber is confident to prescribe the necessary medicines. Prescribers take **legal responsibility for the prescriptions they sign** and they must be prepared to explain and justify their decisions and actions. Clinical responsibility for prescribing is held by the person signing the prescription, who is also responsible for ensuring adequate ongoing monitoring is taking place.

2.13 Health boards should have systems in place to maintain the safe and effective long-term provision of medication within secondary/specialist care or via other primary care prescribers in instances where transfer of prescribing responsibility is declined by the patient's primary care prescriber. This is an essential component of any shared care arrangement. The use of Electronic Prescription Services by hospitals should be encouraged to facilitate this. If a patient must

attend the specialist on a regular basis (for reasons other than obtaining a prescription) then it may be safer and more appropriate for prescribing to be maintained by specialist care.

2.14 It would not normally be expected that a primary care prescriber would decline to prescribe on the basis of medicine cost unless there is a clinically suitable cost-effective alternative available. Likewise if the patient is to receive the majority of their on-going care through secondary care then prescribing should remain within the specialist care setting and must not be transferred solely on the basis of cost or practical considerations of supply.

2.15 Primary care prescribers are not expected to be asked to participate in a shared care arrangement where no national or locally approved protocol exists, or where the medicine falls outside the criteria defined as being suitable for inclusion in a shared care agreement.

2.16 When a primary care prescriber accepts responsibility for prescribing medicines which are not usually dispensed in the community, and where the patient is stabilised on a particular medication, there should be liaison with the transferring hospital, and if appropriate the relevant community pharmacist, to ensure continuity of treatment.

2.17 On occasion, a medicine that has a recognised but unlicensed indication may be considered suitable for shared care. Medicines prescribed off-label (i.e. where the medicine has a marketing authorisation but is used outside of the terms of the licence) may be considered suitable for shared care. For medicines prescribed off-label, use of a shared care protocol should be considered in accordance with GMC guidance on '[Prescribing unlicensed medicines]'[1]. In addition, prescribers must recognise and work within the limits of their competence[5].

2.18 Patients' needs and best interests should be central to the decision to prescribe a medicine via shared care. Clinicians should clearly explain what a shared care arrangement means for the patient, why it might be an option in their case, and the responsibility of the patient to attend appointments and adhere to monitoring arrangements. The patient or their carers should have the opportunity to ask questions and explore other options if they don't feel confident that shared care will work for them. They should be fully involved in, and in agreement with, the decision to move to a shared care model for their ongoing care. Prescribers should ensure that the patient gives informed consent, either verbal or written, and that this is documented within the patient's notes. **Patients should be made aware that their GP has to agree to the shared care request before prescribing is transferred.** Importantly, patients should never be used as a conduit for informing the primary care prescriber that prescribing is to be transferred.

2.19 Involvement of carers may be critical, especially in circumstances when it is not possible for the patient to make a decision e.g. mental capacity; where appropriate they should be included in discussions about shared care. Consenting parties must have sufficient, accurate, timely information in an understandable form. Consent must be given voluntarily and must be documented in the patient's notes.

2.20 The shared care agreement should state how often the patient will be reviewed and provide a 'route of return' should their condition change (such as a return of symptoms, or a development of adverse effects). As part of the consent process, patients must be made fully aware of all monitoring requirements.

2.21 All appropriate monitoring requirements specified within the shared care protocol must be fulfilled. The person delivering that aspect of the shared care agreement should ensure that the resources to do this are in place in the clinical setting in which they are delivered.

2.22 Where community nurse involvement is required in the administration of medicines under a shared care agreement, they should be provided with adequate information and guidance by the prescriber or the specialist and arrangements should be made in good time for any potential problems to be resolved before patient care is compromised.

2.23 Telephone details and (if appropriate) secure email addresses of both parties should be exchanged and recorded. This will enable primary care to access timely advice, guidance and information if problems arise, and also enable secondary care clinicians to easily contact the relevant prescriber in primary care if necessary. This should include out-of-hours contact numbers, e.g. how to access the on-call duty doctor. The *Consultant Connect* app can support prescribers in accessing rapid, clinical advice for patients. Patients and their carers should also be provided with contact details for support and help if required; both in and out of hours.

2.24 Specialists and primary care prescribers should ensure that records of shared care agreements are maintained for each patient for audit purposes, and to enable patient identification and recall. Use of appropriate SNOMED codes may facilitate this.

2.25 All shared care protocols should be based on the current AWMSG template to ensure uniformity of layout and promote familiarity. Similarly, the AWMSG standard shared care agreement form should be used to ensure core essential information is communicated.

3.0 EXAMPLES OF SITUATIONS INAPPROPRIATE FOR SHARED CARE

In some situations the use of shared care is not appropriate and in these cases the specialist should retain responsibility for prescribing. Whilst the situations may be broad and diverse the following would be examples:

3.1 Medicines requiring ongoing specialist intervention and specialist monitoring. Some medicines may have several indications which may require a different status decision depending on the monitoring and assessment required. For example a medicine might be suitable for shared care in one clinical condition whilst remaining specialist for another.

3.2 Patients receiving the majority of ongoing care, including monitoring, from the specialist service and the only benefit of transferring care would be a transfer of costs away from the specialist setting provider costs.

3.3 Medicines that do not have a marketing authorisation within the UK should not be considered for shared care and should only be prescribed in accordance with local health board unlicensed drugs policy.

3.4 Medicines which are only available through specialist routes, i.e. are not available on WP10, including any ‘borderline’ products when used outside approved indications.

3.5 The medicine requires specialist knowledge to safely use or requires long-term on-going specialist monitoring of efficacy or toxicity (either because of difficulty in recognising side effects or high cost/availability of investigations to identify toxicity).

3.6 Where the medicine has no monitoring requirements.

3.7 The medicine is specifically designated as hospital only by nature of the product.

3.8 Medicines prescribed as part of an ongoing hospital based clinical trial, or requiring specialist administration and monitoring using skills or equipment.

3.9 The medicine is not listed in the current BNF or BNFc.

3.10 There is an AWMSG/NICE recommendation that the medicine should not be prescribed on the NHS for the condition specified.

3.11 The treatment is for a patient who will be discharged from ongoing hospital/specialist care and follow up.

3.12 Black Triangle Medicines (unless there is a large body of evidence supporting use e.g. BNF, NICE).

3.13 The medicine cannot be safely administered in primary care.

3.14 The medicine is included in a package of care (e.g. IVF), or requires only a limited course of treatment.

3.15 Where the patient lacks capacity to comply with the shared care guideline and agreement, and there is inadequate supportive care available from a care giver.

REFERENCES

1. General Medical Council. Good practice in prescribing and managing medicines and devices. Prescribing unlicensed medicines. 25 Feburary 2013. Available at: https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines. Accessed January 2021.
2. European Medicines Agency. Available at: https://www.ema.europa.eu/en/glossary/label-use. Accessed January 2021.
3. All Wales Prescribing Advisory Group. Appendix 1. Defining shared care. 2006. Available at: https://awmsg.nhs.wales/files/guidelines-and-pils/shared-care-defining-shared-care-pdf. Accessed January 2021.
4. NHS England Primary Care Delivery - Policy and Strategy OaID. Responsibility for prescribing between Primary and Secondary/Tertiary Care. 2018. Available at: https://www.england.nhs.uk/wp-content/uploads/2018/03/responsibility-prescribing-between-primary-secondary-care-v2.pdf. Accessed January 2021.
5. General Medical Council. Good Practice in Prescribing and Managing Medicine and Devices. 2013. Available at: https://www.gmc-uk.org/-/media/documents/prescribing-guidance_pdf-59055247.pdf?la=en&hash=958C4EED51E3D145EA8798A1AFD85887D3A577B2. Accessed January 2021.

APPENDIX 1: TEMPLATE SHARED CARE PROTOCOL AND SHARED CARE AGREEMENT FORM

<table>
<tr><th colspan="3">PROTOCOL: [DRUG NAME]
This document should be read in conjunction with the current SPC: www.medicines.org.uk/</th></tr>
<tr><td>1. Licensed indications
State if drug is being used off-label.</td><td colspan="2"></td></tr>
<tr><td>2. Therapeutic use and background</td><td colspan="2"></td></tr>
<tr><td>3. Contraindications</td><td colspan="2"></td></tr>
<tr><td>4. Typical dosage regimen (adults)</td><td colspan="2">All dose adjustments will be done by secondary care. The following is for information only:

1. Route
2. Formulation
3. Recommended starting dose----- as a single daily /weekly dose or as divided daily dose
4. Titrate dosage up by ---- (dose)/----- (week or day) according to response.
5. Maintenance dosage up to a maximum ------.
6. Adjunctive treatment regime
7. Conditions requiring dose reduction e.g. impaired renal/ liver function.
8. Usual response time
9. Duration of treatment---------- or as long as indicated by clinical effectiveness</td></tr>
<tr><td>5. Drug interactions
For a comprehensive list, consult the BNF or SPC</td><td colspan="2"></td></tr>
<tr><td rowspan="11">6. Adverse drug reactions
For a comprehensive list (including rare and very rare adverse effects), or if significance of possible adverse event uncertain, consult the SPC or BNF</td><td colspan="2">Most serious toxicity is seen with long-term use and may therefore present first to primary care. The frequency of adverse reactions is classified using the following convention:
Very common (≥ 10%); common (≥ 1% and < 10%); uncommon (≥ 0.1% and < 1%); not known (cannot be estimated from the available data).</td></tr>
<tr><td>Clinical condition (Where possible indicate if common, rare or serious)</td><td>Management (Including threshold at which to contact specialist)</td></tr>
<tr><td>System – symptom/sign</td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td colspan="2">IF YOU SUSPECT AN ADVERSE REACTION HAS OCCURRED, PLEASE STOP THE DRUG/CONTACT THE SPECIALIST DEPARTMENT.
(Delete as appropriate)

The patient should be advised to report any of the following signs or symptoms without delay:
Other important comorbidities (e.g. Chickenpox exposure)

Any adverse reaction to a black triangle drug, or serious reaction to an established drug, should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) via the “Yellow Card” scheme.
https://yellowcard.mhra.gov.uk/</td></tr>
<tr><td>7. Baseline investigations</td><td colspan="2">To be undertaken by secondary care</td></tr>
</table>

8. Monitoring	**Monitoring**	**Frequency**	**Results**	**Action**	**By**
9. Pharmaceutical aspects	E.g. special storage requirements, washout *Or* No special considerations				
10. Advice to patients and carers The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines.					
11. Pregnancy (men and women) and breast feeding It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist.					
12. Secondary care contact information	**If stopping medication or needing advice please contact:** **Dr** **……..** **Contact number:** **……** **Hospital:** **……** **Email:** **……..** **For Out of Hours advice, please telephone:** **……..**				
13. Criteria for shared care	Prescribing responsibility will only be transferred when: • Treatment is for a specified indication and duration. • Treatment has been initiated and established by the secondary care specialist. • The patient's initial reaction to and progress on the drug is satisfactory. • The primary care prescriber has agreed in writing in each individual case that shared care is appropriate. • The patient's general physical, mental and social circumstances are such that he/she would benefit from shared care arrangements.				

14. Responsibilities of initiating consultant	• Initiate treatment. • Undertake baseline monitoring. • Dose adjustments. • Monitor patient's initial reaction to and progress on the drug. • Ensure that the patient is taking their medication and has an adequate supply of medication until primary care supply can be arranged. • Continue to monitor and supervise the patient according to this protocol, while the patient remains on this drug. Provide primary care prescriber with: • Diagnosis, relevant clinical information and baseline results, treatment to date and treatment plan, duration of treatment before consultant review. • Provide primary care prescriber with details of outpatient consultations, ideally within 14 days of seeing the patient, *or* inform primary care prescriber if the patient does not attend appointment. • Advice on when to stop this drug. Provide patient with relevant drug information to enable: • Informed consent to therapy. • Understanding of potential side effects and appropriate action. • Understanding of the role of monitoring. • Monitoring booklet where appropriate.
15. Responsibilities of primary care	• To monitor and prescribe in collaboration with the specialist, according to this protocol. • To ensure that the monitoring and dosage record is kept up to date. • Symptoms or results are appropriately actioned, recorded and communicated to secondary care when necessary. *Delete as appropriate:* Provision of shared care is in accordance with Local Enhanced Scheme, where available. Near-patient testing is in accordance with the service outline of the GMS contract.
16. Responsibilities of patients	• To attend hospital and primary care appointments, including those for monitoring. • Ensure monitoring booklet (if issued) is taken to appointments. • Failure to attend will result in medication being stopped (on specialist advice). • To report adverse effects to their specialist or primary care prescriber.
17. Additional responsibilities	List any special considerations. Responsibilities of all prescribers: Any serious reaction to an established drug should be reported to MHRA.
18. Supporting documentation	Include patient information leaflet if available
19. Patient monitoring booklet	Include patient information leaflet if available
20. Primary care letter	Attached below
21. Guideline date	
22. Guideline review date	

SHARED CARE AGREEMENT FORM

Consultant request

Dear **IMPORTANT: ACTION NEEDED**

Patient name:
Date of birth:
NHS number:
Diagnosis:

This patient is suitable for treatment with (*insert drug name*) for the treatment of *(insert indication).*

This drug has been accepted for Shared Care according to the enclosed protocol (as agreed by Trust/Health Board/AWMSG). **I am therefore requesting your agreement to share the care of this patient, as they are now stable on the treatment**. Where baseline investigations are set out in the shared care protocol, I have carried these out.

Treatment was started on (*insert date started*) (*insert dose*).

If you are in agreement, please undertake monitoring and treatment from *(insert date*).
(NB: date must be at least 1 month from initiation of treatment.)

Baseline tests: *(insert information)*

Next review with this department: *(insert date)*

You will be sent a written summary within (*XX)* days. The medical staff of the department are available at all times to give you advice. The patient will not be discharged from out-patient follow-up while taking *(insert drug name)*.

Please use the reply slip overleaf and return it as soon as possible.

Thank you.

Yours

Signature *Date*

Consultant name

APPENDIX 2: TEMPLATE LETTER – PRIMARY CARE RESPONSE

Dear

Patient: *(Insert Patient's name)*

Identifier: *(Insert Patient date of birth/address/NHS number)*

I have received your request for shared care of this patient who has been advised to start (*insert drug name):*

A I am willing to undertake shared care for this patient as set out in the protocol

B I wish to discuss this request with you

C I am unable to undertake shared care of this patient for the reason(s) below:

	Reason	Tick
1.	**A minimum duration of supply by the initiating physician** As the patient has not had the minimum supply of medication to be provided by the initiating specialist I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until the patient has had the appropriate length of supply the responsibility for providing the patient with their medication remains with you.***	
2.	**Initiation and stabilisation by the initiating specialist** As the patient has not been stabilised on this medication I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until the patient is stabilised on this medication the responsibility for providing the patient with their medication remains with you.***	
3.	**Shared Care Document not received** As legal responsibility for clinical care lies with the doctor who signs the prescription, I need to ensure that I am in possession of sufficient clinical information for me to be confident to prescribe this treatment for my patient and it is clear where each of our responsibilities lie to ensure the patient is safely managed***.*** For this reason I am unable to take clinical responsibility for prescribing this medication at this time, therefore would you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until I receive this information, responsibility for providing the patient with their medication remains with you.***	
4.	**Other (Primary Care Prescriber to complete if there are other reasons why shared care cannot be accepted)**	

Signature of primary care prescriber Date

Contact details (phone number and email):

GP address/practice stamp