

αβχ

δεφγ

ηιφ

κλμ

νοπ

θρσ



Dear Colleague

ADDITIONAL PHARMACEUTICAL SERVICES MINOR AILMENT SERVICE DIRECTIONS AND SERVICE SPECIFICATION

Summary

1. This Circular encloses revised Directions and a revised service specification for the Minor Ailment Service (MAS).

Background

2. NHS Circular PCA (P)(2011) 6 provided revised Directions for Health Board Additional Pharmaceutical Services (Minor Ailment Service). These existing Directions are revoked and replaced by the new 2016 Directions attached at **Annex C**, which come into force as of 1 August 2016. The existing service specification for the MAS is replaced by the new service specification as set out at Schedule 4 of the 2016 Directions.

Detail

3. Following the outcomes of a national exercise into MAS operational practices, the revised Directions and service specification strengthen the requirements of the registration and remuneration processes - reinforcing both the MAS provider (i.e. the community pharmacy contractor) and the pharmacist's responsibilities - in the appropriate provision of MAS including professional and ethical responsibilities, and obtaining patient consent.
4. In addition, **Annex A** sets out supporting key principles that the MAS provider and pharmacist are expected to adhere to when providing MAS and in managing the associated administrative processes. **Annex B** describes the eligibility requirements for MAS.

20 July 2016

Addresses

For action

Chief Executives, NHS Boards
Directors of Pharmacy, NHS
Boards

For information

Chief Executive, NHS NSS

Enquiries to:

Elaine Muirhead
Pharmacy & Medicines Division
1st Floor East Rear
St Andrew's House
EDINBURGH
EH1 3DG

Tel: 0131-244-3433

Email:

Elaine.Muirhead@gov.scot

Patient information

5. The changes do not impact on the patient leaflet, however, this will be kept under review. Pharmacists and MAS providers should ensure that patients are made aware of the service aims and that the patient's or patient's representative's consent has been clearly and specifically obtained before registration using only MAS stationery approved by Scottish Ministers.
6. Patient leaflets continue to be available from APS Group. Additional copies can be ordered by emailing stockorders.DPPAS@apsgroup.co.uk. Translated versions of the leaflet are also available online in Arabic, Polish, Punjabi, Romanian, Slovak and Urdu at <http://www.gov.scot/Publications/2013/09/5918/downloads>.

Funding arrangements

7. There are no changes to the existing payment and funding arrangements for MAS.
8. Community Pharmacy Scotland has been consulted on the contents of this Circular.

Action

9. **Health Boards are asked to note the contents of this Circular and to bring it to the attention of community pharmacy contractors, GPs, local pharmacy committees and Health and Social Care Partnerships.**

Yours sincerely



DR ROSE MARIE PARR
Chief Pharmaceutical Officer/
Deputy Director Pharmacy and Medicines Division

Key Principles for the Provision and Operation of the Minor Ailment Service (MAS)

1. Following a national exercise into MAS operational practices, 10 key principles are now being put in place. In conjunction with the 2016 Directions which encompass the service specification, all MAS providers (i.e. the community pharmacy contractor) and registered pharmacists providing MAS are expected to adhere to these principles.

The 2016 Directions

2. The MAS (Scotland) Directions 2016 ("the 2016 Directions") provide the legal framework for MAS and include four Schedules as follows:
 - Schedule 1: *Services to be provided as a Minor Ailment Service*
 - Schedule 2: *Terms and Conditions for the provision of a Minor Ailment Service*
 - Schedule 3: *Payment for the Minor Ailment Service; and*
 - Schedule 4: *Minor Ailment Service - Service Specification*

The 10 Key Principles

3. The following 10 Key Principles are intended to support the application of the 2016 Directions. The principles are drawn from the content of the directions and, where this is the case, must be adhered to.

Principle 1:
Compliance at all times with the Directions and Service Specification for MAS is essential.

4. All MAS providers and pharmacists providing MAS **must** familiarise themselves with all of the requirements of the 2016 Directions. This is fundamental to the arrangements between the Health Board and the MAS provider for the provisions of MAS.

(Schedule 4, paragraph 1.1)

5. The MAS provider has ultimate responsibility for the appropriate provision of MAS in accordance with all the requirements of the 2016 Directions. These must be complied with at all times.

(Directions, Paragraph 6.2 ; Schedule 2, paragraph 13;
and Schedule 4, paragraphs 1.2)

6. The 2016 Directions and the four Schedules are intrinsically linked. This further emphasises the need for MAS providers and pharmacists providing MAS to familiarise themselves with all aspects of these Directions.

Patient Registration

Principle 2:

MAS providers must not offer incentives to the public or staff, set targets or undertake activity that amounts to a recruitment drive to register patients for MAS

7. A MAS provider **must not** offer any incentives or inducements to the public to register for MAS; offer any incentives or inducements or set targets for pharmacists or staff to recruit people to register for MAS or for any other aspects of MAS.

(Schedule 2, paragraph 1)

Principle 3:

MAS providers and pharmacist(s) must only use approved MAS Stationery and publicity materials

8. Registration must be undertaken using **only MAS stationery approved by Scottish Ministers**. Registration using any other form of document or stationery (e.g. materials produced locally by the MAS provider) is not permitted.

(Schedule 2, paragraphs 3(b) and 7; Schedule 4, paragraph 4.4.1)

9. In addition, **they may only issue or display the publicity material and the patient information leaflet made available by Scottish Ministers in respect of MAS** and the provision of MAS to promote and raise public awareness of the service. Also, if listing MAS on a services offered panel, pharmacy leaflet or website then the MAS provider must not suggest that the service is exclusive to that pharmacy.

(Schedule 2, paragraph 2)

Principle 4:

MAS providers and pharmacist(s) must always obtain the patient's or representative's consent

10. Obtaining and documenting patient (or their representative's) consent to register and receive the associated services is fundamental to the operation of MAS. A pharmacist carrying out a registration must therefore ensure, where applicable, that the patient records their consent by signing the approved MAS stationery.

(Schedule 2, paragraph 3(b))

11. Only under certain circumstances can someone else give consent to registration or treatment on the patient's behalf, or sign the MAS stationery in place of the patient. These circumstances are where:

- The patient is under the age of 16 in which case, the parent or guardian may sign the form.
- Where the patient is the subject of a Power of Attorney or Guardianship Order which allows a named person to give consent.
- The patient is housebound and a representative is attending on their behalf.

(Schedule 4, paragraph 4.3.2)

Housebound Patients

12. Good practice requires that particular care is taken when registering, or providing a MAS consultation to, a patient who is housebound and has arranged for a representative to attend the pharmacy. The MAS provider should ensure that any staff involved in registration of these patients are suitably trained and competent to undertake this process.

13. Registration, or a MAS consultation, for a housebound patient must be carried out in compliance with the directions (as described in paragraph 11 above). The detailed internal process for registration of a housebound patient should be included in a **Standard Operating Procedure** within the pharmacy (see also paragraph 43 of this Annex).

(Schedule 4, paragraph 4.4.2 and 4.9.2)

Principal 5:

MAS stationery should not be signed by MAS providers, pharmacists or support staff on behalf of the patient except in exceptional circumstances.

14. MAS stationery should not be signed by MAS providers, pharmacists or support staff on behalf of the patient except in exceptional circumstances.

(Schedule 4, paragraph 4.4.4)

15. In any exceptional cases where the patient is physically unable to sign, explicit permission must be obtained from the patient and the form should be annotated with name of the signatory (in capitals) and the reason for the proxy signature.
16. In the event where the pharmacy is experiencing IT problems, the pharmacist must complete the appropriate MAS stationery manually and obtain the patient's or patient representative's signature on the form. Once IT functionality is restored an electronic version should be completed and the signed manual form attached.

(Schedule 4, paragraph 4.7.2 - 3)

Patient Eligibility

Principle 6:
MAS providers and pharmacist(s) must always ascertain the patient's eligibility for MAS

17. A patient must be eligible and wish to register for MAS before a MAS provider, pharmacist or member of pharmacy staff commences the registration process.
(Schedule 4, paragraph 4.2.1-2)
18. A MAS provider, pharmacist or member of pharmacy staff should ensure that the required check on a patient's eligibility is made prior to beginning the registration process.
(Schedule 2, paragraph 3(a), Schedule 4 paragraph 4.3.3)
19. As well as checking eligibility at the point of registration, a check must be made at each time the service is accessed thereafter to confirm that there has been no change in circumstances and the person continues to be eligible for MAS.
(Schedule 4, paragraph 4.1.1 and paragraph 4.9.1)
20. If a patient can't provide evidence of their eligibility then the pharmacist should use their professional judgement to determine whether it is appropriate to provide MAS.
21. Patients registering for MAS should mark their eligibility category and sign the back of the MAS stationery. The pharmacist should sign the front of the form.

(Schedule 4, paragraph 4.3)

The Electronic Recording of Registrations - eMAS

Principle 7:

MAS providers and pharmacist(s) should always record complete and accurate patient information

22. Only once a patient or patient representative has given their agreement to register for MAS, and appropriate eligibility checks have been carried out, can a MAS provider, pharmacist or member of pharmacy staff begin the registration process.
23. The following information is required to support the registration of a patient electronically using eMAS (PMR systems all support this through their eMAS programmes):
- Full Name
 - Postcode
 - Date of birth
 - Gender
 - CHI Number
28. It is important that this information is complete and accurate, for example the postcode is correct and properly populated in the correct information field.
- (Schedule 4, paragraph 6.7)*
29. A patient's exemption category should also be recorded and confirmed each time a consultation is carried out in order to ensure that they are still eligible for MAS.
30. A patient record must be established and retained as part of the registration process which includes as a minimum:
- the patient's name and address;
 - the name and address of the person who gave consent to, or applied for, the registration and their relationship to the patient who is registered, where appropriate;
 - the reason for the patient's eligibility to register for MAS, i.e. their exemption status;
 - the services provided to the registered patient as MAS, to include:
 - details of the treatment provided;
 - a record that advice only or a referral has been provided as an alternative to treatment and the associated date;
 - the date on which each of the above was provided; and

- with respect to treatments, the name, quantity, form and strength of any product supplied.

(Schedule 2, paragraph 3(d) and 4)

31. Pharmacists and their staff should ensure that the information printed on MAS stationery is in the correct position and that this information is readable. Forms should be reprinted prior to signing if this is not the case. Note that this is reprinting of the form and not re-registering the patient. All PMR systems have the facility to reprint forms.

Principle 8:

MAS providers and pharmacist(s) should not 'batch' register patients for MAS other than in exceptional circumstances

32. MAS providers should not 'batch' register patients for MAS. The exception to this is where there has been an IT problem meaning electronic data capture has not been possible and the forms have had to be completed manually. Where this is the case then the pharmacist must notify the ePharmacy Helpdesk before they start to enter registrations or activities by batch and provide an estimate of registrations and consultations which have been delayed.

(Schedule 4, paragraph 6.8)

33. If access to the PRS is not available, a blank MAS stationery form should be completed manually and signed by the patient. Manual registration for MAS using this method is regarded as the exception; the normal route for registration is using electronic data exchange (eMAS).

(Schedule 4, paragraph 4.7.2)

34. In cases where manual registration has been necessary, the data must be entered electronically and forms generated. The signed manual forms should be attached to the associated electronically generated forms and submitted to PSD.

(Schedule 4, paragraph 4.7.3)

35. MAS providers and pharmacist(s) requiring to complete the MAS registration form manually should first contact the ePharmacy Helpdesk (0131 275 6600) indicating the reason why and when this use is expected to start and also when electronic submission of registrations will start / resume.

Deadline for Submission of MAS Stationery used for registration

36. MAS stationery used for MAS registration must be submitted within **two months** of the date of registration. The electronic message will be matched to the associated form and registrations may be cancelled if no form has been submitted within two months of registration.

(Schedule 4, paragraph 6.6)

37. The blank right hand side of the MAS stationery form should be torn off and discarded prior to submission to PSD.

38. Incomplete registration forms should not be submitted to PSD.

(Schedule 4, paragraph 6.7)

Principle 9:

“Lapsed registrations” can only be reactivated if the patient uses the service

39. If a MAS registered patient has not accessed the service for 12 months, their registration will lapse and will not count towards the monthly total for that MAS provider.

(Schedule 4, paragraphs 4.6.1)

40. These “lapsed” registrations can only be reactivated if the patient accesses and uses the service at that pharmacy at a later date for a MAS consultation. MAS providers, pharmacists and members of pharmacy staff **must not attempt to reactivate registrations if patients have not used MAS.**

(Schedule 4, paragraphs 4.1.17 to 19)

41. All registration activity, including re-activation of a lapsed registration, **must be** based on direct contact with the patient or patient’s representative by either the pharmacist, or by a member of pharmacy staff under the direct supervision of the pharmacist.

(Schedule 4, paragraph 4.2.2)

42. If a patient registration has lapsed and they subsequently wish to access the service, the patient is required to confirm that they remain eligible for MAS and sign the appropriate MAS stationery form.

(Schedule 4, paragraph 4.6.3)

Principle 10:

MAS providers and pharmacist(s) must at all times operate MAS professionally and ethically and in the best interest of the patient

43. MAS providers should ensure that there is a comprehensive Standard Operating Procedure (SOP) for MAS which covers all aspects of service provision including registration, registration of housebound patients, withdrawal, consultation and treatment.
44. All providers of NHS services have a duty to use NHS resources responsibly and these should be only used in the best interest of the patient. In the case of MAS, this includes registration and treatment, covering remuneration for the provision of the service as well as reimbursement of the items dispensed and provided through the service.
45. MAS providers are obliged to provide the right environment to allow pharmacists to provide professional clinical care as they consider appropriate to the patient.
46. The supply of a medicine should be in response to a patient consultation and only when it is the most clinically appropriate intervention.

(Schedule 4, paragraph 4.9.6)

Post Payment Verification

47. As with all pharmacy payments, MAS claims will be subject to scrutiny by Practitioner Services' Payment Verification (PV) team. Any anomalies or outliers will be investigated by PV and, where appropriate, will be referred to the relevant NHS Board, and to NHSScotland Counter Fraud Services (CFS).
48. MAS providers who submit an unsatisfactory response or fail to respond to payment verification enquiries may be considered for onward referral and/or financial recovery.
49. Where after suitable investigation an NHS Board is satisfied that a MAS provider has not provided the services in accordance with the 2016 MAS Directions it can suspend payments for MAS and recover those made in respect of any appropriate period(s).

(Schedule 4, paragraphs 7.3-7.5)

**Pharmacy and Medicines Division
Healthcare Quality and Strategy Directorate
Scottish Government
July 2016**

Eligibility requirements for MAS

The following persons are eligible for the service:

- persons who are under 16 years of age
- persons who are under 19 years of age and in full-time education;
- persons who are 60 years of age or over;
- persons who have a valid maternity exemption certificate, medical exemption certificate, or war pension exemption certificate;
- persons who get Income Support, Income-based Jobseeker's Allowance, Income-related Employment and Support Allowance, or Pension Credit Guarantee Credit, and their family members;
- persons who receive Universal Credit, subject to certain income thresholds, and their family members;
- persons who receive support because they are asylum-seekers, and their family members; and
- persons who are named on, or are entitled to, an NHS tax credit exemption certificate or a valid HC2 certificate.

The following persons are not eligible:

- persons who are not included in the list of eligible persons above;
- persons who are listed above but who are either not registered with a Scottish GP practice, or are only registered with a Scottish GP practice as a temporary resident;
- persons who are listed above but are resident in a care home.

NATIONAL HEALTH SERVICE (SCOTLAND) ACT 1978

HEALTH BOARD ADDITIONAL PHARMACEUTICAL SERVICES (MINOR AILMENT SERVICE) (SCOTLAND) DIRECTIONS 2016

The Scottish Ministers, in exercise of the powers conferred by sections 2(5), 27A, 27B, and 105(6) and (7) of the National Health Service (Scotland) Act 1978¹, and all other powers enabling them to do so, give the following Directions.

1. Citation and commencement

1.1 These Directions may be cited as the Health Board Additional Pharmaceutical Services (Minor Ailment Service) (Scotland) Directions 2016 and come into force on 1 August 2016.

2. Interpretation

2.1 In these Directions, unless the context otherwise requires:

“the Act” means the National Health Service (Scotland) Act 1978;

“the 2009 Regulations” means the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009²;

“the 2011 Directions” means the Health Board Additional Pharmaceutical Services (Minor Ailment Service) (Scotland) Directions 2011;

“the 2011 Regulations” means the National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Scotland) Regulations 2011³;

“approved appliance” means an appliance which has been approved by the Practitioner Services Division of the Common Services Agency for provision under MAS;

¹ 1978 c.29; section 2(5) was amended by the National Health Service and Community Care Act 1990 (c.19), section 66(1) and Schedule 9, para. 19(1); section 27A was inserted by the National Health Service (Primary Care) Act 1997 (c.46) (“the 1997 Act”), section 27(2); section 27B was inserted by the 1997 Act, section 28(2); section 105(7) was amended by the Health Services Act 1980 (c.53), section 25(3) and Schedule 6, paragraph 5(1) and Schedule 7, the Health and Social Services and Social Security Adjudications Act 1983 (c.41), section 29(1) and Schedule 9, Part I, paragraph 24 and by the 1999 Act, section 65 and Schedule 4, paragraph 60. The functions of the Secretary of State were transferred to the Scottish Ministers by virtue of section 53 of the Scotland Act 1998 (c.46).

² S.S.I. 2009/183, amended by S.S.I. 2009/209, S.S.I. 2010/128, S.I. 2010/231, S.S.I. 2011/32, S.S.I. 2011/55, S.S.I. 2012/36, S.I. 2012/1916, S.I. 2012/1479, S.I. 2012/2041, S.I. 2013/235, S.S.I. 2014/73, S.S.I. 2014/148 and S.I. 2015/968.

³ S.S.I. 2011/55, amended by S.S.I. 2012/74, S.S.I. 2013/191, S.S.I. 2014/115 and S.S.I. 2015/160.

“care home” means an establishment which provides a care home service as defined in paragraph 2 of schedule 12 to the Public Services Reform (Scotland) Act 2010⁴;

“consultation” means a consultation with a pharmacist under the Minor Ailment Service;

“eligible person” means a person who at the time of initial registration, and at the time of any subsequent consultation, falls within the following categories of person:

- (a) a person who is under the age of 16 years;
- (b) a person who is under the age of 19 years and is receiving qualifying full time education within the meaning of paragraph 7 of Schedule 11 to the Act⁵;
- (c) a person who is 60 years of age or over;
- (d) a woman to whom a Health Board has issued an exemption certificate on the ground that she is an expectant mother or has within the last 12 months given birth to a live child or a child registrable as still-born under the Registration of Births, Deaths and Marriages (Scotland) Act 1965⁶;
- (e) a person with a valid exemption certificate;
- (f) a person to whom the Secretary of State has issued a valid exemption certificate in respect of the supply of drugs and appliances for the treatment of accepted disablement but only in respect of those supplies to which the certificate relates;
- (g) a person who falls within the categories of person specified in regulation 4(2) of the National Health Service (Travelling Expenses and Remission of Charges) (Scotland) Regulations 2003⁷;

except that a person who would be eligible by virtue of (a) to (g) is not an eligible person if that person is:

- (i) not registered on a permanent basis with a GP in Scotland; or
- (ii) a person whose main or usual residence is a care home,

and “eligible persons” shall be construed accordingly.

⁴ 2010 asp 8.

⁵ Para. 7 of Schedule 11 was inserted by the Health Services Act 1980 (c.53), section 26(2) and Schedule 5, Part II, para. 8. 8.

⁶ 1965 c.49. The definition of ‘still-born child’ in section 56 of that Act was amended by the Still-Birth (Definition) Act 1992 (c.29), section 1(2).

⁷ S.S.I. 2003/460 (revoking S.S.I. 2003/376). Regulation 4 was amended by S.S.I. 2004/102, S.S.I. 2004/166, S.S.I. 2005/179, S.S.I. 2007/225, S.S.I. 2007/259, S.S.I. 2008/27, S.S.I. 2008/228, S.S.I. 2009/124, S.S.I. 2011/55, S.S.I. 2013/137, S.S.I. 2013/142 and S.S.I. 2015/333.

“exemption certificate” means a certificate issued by a Health Board to a named patient under Regulation 4 of the 2011 Regulations;

“General Sales List (GSL) Medicine” has the meaning ascribed to “medicinal product subject to general sale” by regulation 5(1) of the Human Medicines Regulations 2012⁸;

“MAS provider” means a person with whom a Health Board has made arrangements for the provision of a Minor Ailment Service as described in paragraph 5.1;

“Minor Ailment Service” or “MAS” has the meaning ascribed in paragraph 3.1;

“Minor Ailment Service stationery” or “MAS stationery” means forms, approved by Scottish Ministers, on which -

- (a) the details of a patient registered for MAS are recorded; or
- (b) the details of a registered patient’s MAS transactions are recorded, including:
 - (i) any consultation undertaken;
 - (ii) any supply of medicine or appliance; and
 - (iii) any referral to another healthcare practitioner;

“patient record” means a record maintained for each recipient of MAS in accordance with paragraph 4 of Schedule 2;

“patient group direction” or “PGD” has the meaning ascribed to it in regulation 213(1) of the Human Medicines Regulations 2012;

“pharmacist” means a person who is registered as a pharmacist in Part 1 or 4 of the register maintained under article 19 of the Pharmacy Order 2010⁹ or the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976¹⁰

“Pharmacy (P) medicine” has the meaning ascribed to “pharmacy medicine” in article 1 of the Medicines (Pharmacy and General Sale-Exemption) Order 1980¹¹;

“registration” means registration for the Minor Ailment Service in terms of paragraphs 3 to 5 of Schedule 2, and “registered” shall, except where the context otherwise requires, be construed accordingly ;

“Yellow Card reporting mechanism” means an arrangement set up for reporting adverse reactions to medicines to the Medicines and Healthcare products Regulatory Agency on pre-printed and postage paid yellow cards, or to www.yellowcard.gov.uk.

2.2 A person is registered on a permanent basis with a GP in Scotland if that person is:

⁸ S.I. 2012/1916.

⁹ S.I. 2010/231

¹⁰ S.I. 1976/1213 (N.I. 22)

¹¹ S.I. 1980/1924

(a) a registered patient in terms of the National Health Service (General Medical Services Contracts) (Scotland) Regulations 2004¹²;

(b) a registered patient in terms of the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004¹³; or

(c) otherwise registered (other than as a temporary resident) to receive primary medical services in terms of the Act.

2.3 Other words and phrases used in these Directions have the same meaning as they have in the Act and in the 2009 Regulations.

2.4 Any reference in these Directions

(i) to a numbered paragraph, is a reference to a paragraph bearing that number in these Directions;

(ii) to a numbered Schedule, is a reference to the Schedule to these Directions bearing that number; and

(iii) to a numbered paragraph of a numbered Schedule, is a reference to a paragraph bearing that number in the Schedule bearing that number.

3. Description of the Minor Ailment Service

3.1. The Minor Ailment Service is a service for the provision of pharmaceutical care to persons who are registered to receive MAS by a person who is authorised to provide MAS in terms of paragraph 5 and, where appropriate, advice, treatment or onward referral by that person to another NHS healthcare practitioner.

3.2 The services which comprise MAS are specified in Schedule 1 and Schedule 4.

4. Health Board duty to arrange for a Minor Ailment Service

4.1 Until otherwise directed, Health Boards have a duty to arrange for the provision of Minor Ailment Services (MAS) for persons in their area as additional pharmaceutical services.

4.2 Health Boards must inform MAS providers of the formulary or prescribing guidelines that apply to the provision of MAS in their area. The products that a Health Board may include on their formulary are:

(i) (Pharmacy (P) and General Sales List (GSL) medicines that are not listed in directions given by Scottish Ministers under section 17N(6) of the Act as to drugs, medicines or other

¹² S.S.I. 2004/115. Regulation 2 defines “registered patient”.

¹³ S.S.I. 2004/116. Regulation 2 defines “registered patient”.

substances which may or may not be ordered for a patient in the provision of primary medical services¹⁴ (the “black list”);

(ii) dressings and appliances from Part 2 of the Drug Tariff;

(iii) approved appliances from Part 3 of the Tariff; and

(iv) any Prescription Only Medicines (POMs) that are detailed in a Patient Group Direction in relation to MAS.

5. Persons authorised to provide the Minor Ailment Service

5.1 Health Boards may only enter into arrangements for the provision of MAS with:

(a) a pharmacist; or

(b) a person other than a pharmacist who, by virtue of section 69 of the Medicines Act 1968¹⁵, is taken to be a person lawfully conducting a retail pharmacy business in accordance with that section;

and, in the case of both (a) and (b) who:

(i) is on the pharmaceutical list maintained by the Health Board in terms of regulation 5 of the 2009 Regulations¹⁶; and

(ii) undertakes that all MAS shall be provided either by or under the direct supervision of a pharmacist.

6. Compliance and Conditions

6.1 The arrangements made by a Health Board in accordance with paragraphs 4 and 5 shall include the imposition of the terms and conditions specified in Schedule 2, with which the MAS provider must comply.

6.2 Where a MAS provider requires a pharmacist to provide MAS, the MAS provider has ultimate responsibility for ensuring that the MAS service is provided in accordance with these Directions.

7. Payment for the provision of a Minor Ailment Service

7.1. Remuneration for the provision of MAS will be paid at nationally negotiated rates as set out in the Drug Tariff and in accordance with Schedule 3 of these Directions.

¹⁴ Directions of the Scottish Ministers as to the drugs, medicines or other substances which may, or may not, be ordered for patients in the provision of primary medical services under a general medical services contract were issued on 9 February 2011.

¹⁵ 1968 c.67. Section 69 was amended by the Pharmacists (Fitness to Practise) Act 1997 (c.19), section 1 and paragraph 5 of the Schedule, by the Statute Law Repeals Act 1993 (c.50), Schedule 1 (XII), para. 1 and by S.I. 2007/289, S.I. 2007/3101 and S.I. 2010/231.

¹⁶ Regulation 5 was amended by S.S.I. 2011/32 and S.S.I. 2014/148

7.2. The prices and methodology for calculating reimbursements to a MAS provider for any preparations or appliances that he or she may supply to patients registered for MAS in connection with providing MAS will be in accordance with the provisions set out in Part 1 of the Drug Tariff.

8. The Health Board Additional Pharmaceutical Services (Minor Ailment Service) (Scotland) Directions 2011

8.1 These Directions revoke and supersede the 2011 Directions.

8.2 Notwithstanding paragraph 8.1, the 2011 Directions shall continue to apply in respect of any MAS provided on or before 31 July 2016.

Signed by authority of the Scottish Ministers

Dr Rose Marie Parr
Scottish Executive
A member of the Senior Civil Service
20 July 2016

NATIONAL HEALTH SERVICE (SCOTLAND) ACT 1978

**HEALTH BOARD ADDITIONAL PHARMACEUTICAL SERVICES (MINOR
AILMENT SERVICE) (SCOTLAND) DIRECTIONS 2016**

SCHEDULE 1

SERVICE TO BE PROVIDED AS A MINOR AILMENT SERVICE

1. The service comprises a consultation with a pharmacist and advice on the condition(s) that the patient or patient's representative presents and, where the pharmacist considers it appropriate, the supply of preparations or appliances for its treatment. Where the pharmacist considers the condition is one that requires to be considered by another member of the primary care team (e.g. a GP), the pharmacist will refer the patient to that person.

NATIONAL HEALTH SERVICE (SCOTLAND) ACT 1978

HEALTH BOARD ADDITIONAL PHARMACEUTICAL SERVICES (MINOR AILMENT SERVICE) (SCOTLAND) DIRECTIONS 2016

SCHEDULE 2

TERMS AND CONDITIONS OF THE PROVISION OF A MINOR AILMENT SERVICE

1. A MAS provider must not offer any incentives or inducements to the public to register for MAS; offer any incentives or inducements or set targets for employee pharmacists or staff to recruit people for MAS or for any other aspects of MAS.
2. A MAS provider may only issue or display the publicity material and patient information leaflet made available by Scottish Ministers in respect of MAS and the provision of MAS to promote and raise public awareness of the service.
3. Where a person is an eligible person and wishes to register for the service, a MAS provider must ensure that the registration process is undertaken in accordance the procedures set out in Schedule 4, and in particular that:
 - (a) evidence is seen to confirm the person's eligibility;
 - (b) only MAS stationery approved by Scottish Ministers is used for the registration process;
 - (c) the patient's, or their representative's agreement to register has been obtained and recorded; and
 - (d) a patient record is established.
4. For the purposes of MAS the 'patient record' is a pharmacy retained record (paper and/or electronic) that as a minimum must include:
 - (a) the name and address of the patient;
 - (b) where relevant, the name and address of the person who gave consent to, or applied for, the registration and that person's relationship to the person who is registered;
 - (c) the grounds for the patient's eligibility for MAS;
 - (d) the date of each MAS consultation; and
 - (e) the services provided to the registered patient as MAS, to include:
 - (i) information on whether advice, treatment or onward referral was provided;
 - (ii) details of any treatment provided; and
 - (iii) the name, quantity, form and strength of any product supplied.
5. MAS can be provided to a patient only from the premises at which the patient is registered for MAS.
6. Subject to the provisions of any Regulations made under section 69 of the 1978 Act, all drugs, containers and appliances supplied for MAS shall be supplied free of charge.

7. A MAS provider is to use MAS stationery approved by Scottish Ministers to record details of a consultation where a patient registered for MAS:

- (i) receives advice;
- (ii) is supplied with medicines and appliances for treatment purposes;
- (iii) is referred to another healthcare practitioner; or
- (iv) is no longer eligible for MAS and registration must be withdrawn.

8. Where a MAS provider supplies medicines, dressings and appliances he or she must have regard to any local formulary that the Health Board applies.

9. The products that may be supplied under MAS are:

- (i) (Pharmacy (P) and General Sales List (GSL) medicines that are not listed in directions given by Scottish Ministers under section 17N(6) of the Act as to drugs, medicines or other substances which may or may not be ordered for a patient in the provision of primary medical services (the “black list”);
- (ii) dressings and appliances from Part 2 of the Drug Tariff;
- (iii) approved appliances from Part 3 of the Tariff; and
- (iv) any Prescription Only Medicines (POMs) that are detailed in a Patient Group Direction in relation to MAS.

10. The supply of medicines, dressings or appliances is to be performed by or under the direct supervision of a pharmacist.

11. The pharmacist referred to in paragraph 10 must not be one:

- (a) who has been disqualified under section 29B(2) of the Act¹⁷, or
- (b) who is suspended by direction of the Tribunal, or
- (c) who is the subject of a corresponding decision in England, Wales or Northern Ireland.

12. In providing MAS, a MAS provider shall do so:

- (a) in compliance with all procedures and processes described in the service specification included at Schedule 4 of these directions;
- (b) having regard to and, where required, in compliance with, stated standards and administrative guidance that is from time to time produced by Scottish Ministers; and
- (c) in conformity with the standards generally accepted in the pharmaceutical profession.

¹⁷ Section 29B was inserted by the 1999 Act, section 58, and amended by the Community Care and Health (Scotland) Act 2002 (asp 5), section 25 and Schedule 2, paragraph 2(6), the Primary Medical Services (Scotland) Act 2004 (asp 1), section 8 and Schedule 1, paragraph 1(13), and by the Smoking, Health and Social Care (Scotland) Act 2005 (asp 13), section 26 and Schedule 3.

13. The provisions at paragraph 12 of Schedule 1 of the 2009 Regulations, as amended, with regard to and referred to as a “complaints procedure” shall apply to the provision of MAS.

14. A MAS provider must ensure that—

- (a) where that MAS provider is an individual, that they provide MAS in accordance with these Directions; and
- (b) where a MAS provider requires a pharmacist to provide MAS, that the pharmacist provides the MAS service in accordance with these Directions.

NATIONAL HEALTH SERVICE (SCOTLAND) ACT 1978

HEALTH BOARD ADDITIONAL PHARMACEUTICAL SERVICES (MINOR AILMENT SERVICE) (SCOTLAND) DIRECTIONS 2016

SCHEDULE 3

PAYMENT FOR THE MINOR AILMENT SERVICE

1. Where a MAS provider complies fully with these Directions, payment for the provision of a Minor Ailment Service will be paid monthly in arrears at the rates set out in the Drug Tariff.
2. Capitation payments will be calculated on the number of patients registered with the MAS provider for MAS on the last day of each month.
3. (a) Where a person registered to receive MAS is no longer an eligible person, the MAS provider with whom that person is so registered must terminate that registration as soon as that change in status is known by the provider. In the event that the provider fails to do so, the Agency shall be entitled to refuse to make any payment in respect of MAS to the provider in respect of that person.

(b) Notwithstanding sub-paragraph (a) of this paragraph, in the event that the Agency is made aware that a person registered to receive MAS is no longer eligible, the Agency will terminate that registration as soon as that change in status is known, and notify the relevant provider accordingly.
4. A registered person whose registration is deemed lapsed shall not be included in the number of registered patients on which the capitation payment is calculated.
5. A person whose registration for MAS was deemed lapsed but whose registration is reactivated shall be included in the number of registered patients of a MAS provider on which the capitation payment is calculated with effect from the last day of the month in which the reactivation occurs.
6. Confirmation of patient registration and withdrawal, and claims for reimbursement of any medicines or appliances supplied to a registered patient, are to be made on MAS stationery and submitted within every two months to Practitioner Services Division of the Common Services Agency (NHS National Services Scotland) by the dates it specifies.
7. Health Boards will be entitled to take such reasonable steps as are necessary to ensure that MAS providers are:
 - (a) providing MAS as specified in Schedule 1 and complying with the provisions of Schedules 2 and 4; and
 - (b) only displaying the agreed patient information leaflets and publicity materials made available by Scottish Ministers in respect of MAS.

8. Payments made to MAS providers for providing MAS will be subject to post-payment verification checks and investigation by the Agency.

9. Where after suitable investigation a Health Board is satisfied that a MAS provider is not providing the services listed in Schedule 1 and/or complying with the provisions of Schedules 2 and 4, but is receiving payment in terms of this Schedule and the rates set out in the Drug Tariff, it may (without prejudice to any other action which may be open to it):

- (a) write to the MAS provider advising of the conclusion reached by the investigation;
- (b) inform the MAS provider that payments will be stopped with immediate effect;
- (c) recover any payments made to the provider under this Schedule and the Drug Tariff in respect of any period(s) when the MAS provider was not providing the services specified in Schedule 1 and/or complying with the provisions of Schedules 2 and 4.
- (d) in exceptional circumstances, such as deliberate or repeated non-compliance with the provisions of Schedules 2 and 4, withdraw the service from the MAS provider and notify the General Pharmaceutical Council.

NATIONAL HEALTH SERVICE (SCOTLAND) ACT 1978

HEALTH BOARD ADDITIONAL PHARMACEUTICAL SERVICES (MINOR AILMENT SERVICE) (SCOTLAND) DIRECTIONS 2016

SCHEDULE 4

MINOR AILMENT SERVICE (MAS) SERVICE SPECIFICATION

1. Introduction

1.1 The MAS provider and any pharmacist(s) providing MAS on behalf of a MAS provider must familiarise themselves with the requirements of these Directions.

1.2 The MAS provider and any pharmacist(s) providing MAS on behalf of a MAS provider must provide the MAS service in compliance with the requirements of these Directions.

1.3 The terms and conditions of the provision of MAS apply to each MAS provider in accordance with paragraph 6.1 of the Directions. The pharmacist also has a professional responsibility to ensure the ethical provision of the service and that it is provided in the best interest of the patient at all times.

2. Service Aim and Objectives

2.1 The aim of the MAS is to support the provision of direct pharmaceutical care on behalf of the NHS by pharmacists to members of the public presenting with a common self-limiting illness.

2.2. The core objectives for MAS are to:

- improve access to healthcare consultations, advice, medicines and appliances for common or minor illnesses;
- promote pharmaceutical care through the community pharmacy setting;
- assist in managing the demand on the time of other members of the primary healthcare team by shifting the balance of care from GPs and nurses to community pharmacists where appropriate;
- help address health inequalities.

3. Service Description

3.1 MAS allows eligible individuals to register with and use their community pharmacy as the first port of call for the consultation and treatment of common self-limiting illnesses. The pharmacist advises, treats or refers the patient according to their needs.

4. Service Components

4.1 Eligibility

4.1.1 A person is eligible for MAS where they are a person who at the time of initial registration, and at the time of any subsequent consultation comes within the categories of person defined as an “eligible person” in Paragraph 2 of the Directions.

4.1.2 Patients resident in care homes are not eligible for MAS, even if they would otherwise be within the definition of an “eligible person”.

4.2 MAS Registration

4.2.1 Individuals who are eligible for MAS can register with a community pharmacy of their choice to receive MAS.

4.2.2 Registration without direct contact from a patient or patient’s representative is not permitted.

4.2.3 Once a patient has registered at a pharmacy, that patient may access the MAS service at that pharmacy at any time provided that the patient remains an “eligible person” and has not withdrawn from the service.

4.2.4 If the patient wishes to access the MAS service at a different pharmacy they must register with that pharmacy. Registration with a pharmacy automatically withdraws the patient from registration with any previous pharmacy.

4.3 The Registration Process

4.3.1 A registration process which complies with this service specification must be used for all MAS registrations.

4.3.2 The registration process requires MAS Stationery to be completed by the pharmacist or trained staff under direct supervision of the pharmacist.

4.3.3 The pharmacist carrying out the registration must check that the person is eligible for MAS. Evidence (for example proof of date of birth or entitlement to a particular benefit) should be requested to confirm eligibility.

4.3.4 The patient must complete the registration process in person except in the following circumstances:

- Where the patient is a child under 16. In that case, the patient’s parent or guardian should complete the registration process on behalf of the patient. The patient may or may not be present during the registration.
- Where the patient is over 16 but is unable to make decisions about their own medical care due to an illness, impairment, or disability, and has formally appointed a proxy

decision maker (for example using a Power of Attorney or a Guardianship). In that case, the patient's appointed decision maker should complete the registration process on behalf of the patient. The patient may or may not be present during the registration.

- Where the patient is unable to attend the pharmacy in person because of their symptoms or because they are housebound due to a disability or illness. In that case, they may authorise a relative or friend to attend the pharmacy and carry out the registration process.

4.4 Documenting registration

4.4.1 Registration must be undertaken using only MAS stationery approved by Scottish Ministers. Registration using other documentation, for example materials produced by the MAS provider, is not permitted.

4.4.2 A fundamental part of the MAS stationery is the requirement for signature to confirm the patient's consent to the registration. It is a requirement of the registration process that the pharmacist or member of staff carrying out a registration must ensure an appropriate signature is provided as follows:

- Where the patient is present in the pharmacy, or where a member of pharmacy staff visits the patient to complete the registration, the patient should sign the MAS stationery.
- Where the patient is a child, or an adult with a legally appointed guardian or attorney, the patient's parent, guardian or legal representative should sign the MAS stationery to confirm consent to the registration on the patient's behalf.
- Where the patient is not present and has authorised someone to complete the MAS registration on their behalf, the authorised person should sign the MAS stationery. The form should be annotated to record why the patient has not signed the form themselves, and to record information about the person acting on behalf of the patient.
- Where the patient is physically unable to sign, explicit permission must be obtained from the patient and the MAS stationery should be annotated with the name of the signatory (in capitals) and the reason for the proxy signature.

4.4.3 The patient or patient's representative should mark the applicable eligibility category and sign the back of the MAS stationery. The pharmacist or member of staff carrying out the registration should sign the front of the form.

4.4.4 Pharmacy staff should not sign a form on behalf of the patient except in very limited circumstances, such as where the patient is present for the registration and is able to give consent to the registration, but is unable to physically sign the form. Instances of this are likely to be rare.

4.5 Registration of patients from residential schools

4.5.1 Patient representatives seeking MAS registration on behalf of patients from a residential school must have the appropriate authority to provide consent on behalf of the patient, in place of the patient's parent or guardian.

4.6 Lapsed Registration

4.6.1 A patient's registration is deemed lapsed if they have not used MAS for 12 months.

4.6.2 A lapsed registration may only be reactivated if the patient accesses the service. It should not be reactivated without the patient's consent or in advance of the patient accessing the service.

4.6.3 If a patient's registration has lapsed and they subsequently wish to access the service, they will be required to declare that their eligibility for the service remains valid and then sign the appropriate MAS stationery form.

4.7 Electronic Recording of the Registration - eMAS

4.7.1 A patient is registered for MAS via the Patient Registration System (PRS) hosted at the Common Services Agency (NHS National Services Scotland) utilising the Community Health Index (CHI) number. This, in turn, triggers the printing of a paper MAS registration form in the pharmacy which the patient/patient's representative signs as set out at paragraph 4.2 above.

4.7.2 If access to the electronic registration system is not available, a blank MAS stationery form must be completed manually and signed by the patient or patient's representative. Manual registration for MAS using this method is regarded as the exception; the normal route for registration is using electronic data exchange (eMAS).

4.7.3 In cases where manual registration has been necessary, the data must be entered electronically and electronic forms generated. The signed manual form should be attached to the associated electronic form and submitted to Practitioner Services Division.

4.8 Withdrawal

4.8.1 Patients can choose to withdraw from MAS at any point. In addition, pharmacists can withdraw a patient; this might be due to, for example, a change in their eligibility or other exceptional circumstances. The Patient Registration System (PRS) withdraws people automatically if they die or move into a care home. Registering at a different pharmacy automatically withdraws the individual from a pharmacy where they have been previously registered.

4.9 MAS Consultation

4.9.1 Care provided through MAS includes the presentation, assessment and treatment of symptoms. The pharmacist confirms the eligibility of the patient for MAS, assesses the

patient and considers the most appropriate course/s of action, the counselling and advice needs and any requirements for follow up or referral. The consultation must be provided by the pharmacist in person or by trained staff under the direct supervision of the pharmacist.

4.9.2 A patient should normally present with a symptom(s) in person or, occasionally, a representative may present on their behalf. For example, a parent or guardian could attend a MAS consultation on behalf of a child. If a registered adult patient is housebound due to an illness, frailty or disability, a relative or friend may attend a consultation on behalf of the patient.

4.9.3 Where the patient is not present, the pharmacist is to use their professional judgement to determine what, if any, advice or treatment can be provided without seeing the patient in person.

4.9.4 The pharmacist assesses the symptoms in order to ascertain and consider information which helps them to determine the cause and severity of the presenting condition and determine the most appropriate course of action. This includes the differentiation between common illness and major disease. This helps the pharmacist to decide on the most appropriate form of action. This can be advice only, treatment or referral.

4.9.5 In some instances the only course of action required is to provide advice to a patient. This may also include aspects of healthy lifestyle advice.

4.9.6 When the pharmacist decides that the most appropriate action is to treat the presenting condition(s) then they will then decide on the course of treatment they wish to recommend for the patient. The supply of a medicine or appliance should be in response to a patient consultation and only provided when it is the most clinically appropriate intervention.

4.9.7 The pharmacist will also establish the counselling and advice needs of the patient. This includes explaining what to expect from their condition, what treatment is being prescribed for them, how to use that treatment, any follow up and how to avoid future episodes. This process is underpinned by the CRAG *Counselling and Advice Guidelines*.

4.9.8 The requirement to refer a patient is, in most instances, obvious when assessing the condition. Pharmacists and GPs should agree locally the circumstances when and procedure by which a patient requiring to be seen quickly can be referred and this should be supported using either a verbal or written referral request. Patients may also self-refer to their GP.

4.9.9 The MAS consultation enables the pharmacist to identify and agree a shared outcome or a set of outcomes with the patient. This happens as a result of the systematic approach applied to MAS.

4.9.10 The pharmacist also considers the requirement or need for any further follow up. Follow up involves looking for signs that the condition is improving and that there is no deterioration. This is carried out by the patient with any necessary information or support provided by the pharmacist or a member of their support staff.

5. Formulary

5.1 The products that are recommended to be supplied under MAS by the Pharmacist are listed in formularies applied for that purpose by the Health Board.

5.2 The applicable Health Board formulary may include any of the products which are available for provision under MAS, as specified in paragraph 9 of schedule 2 to the Directions.

5.3 Where a pharmacist providing MAS considers it appropriate to provide a product which is not listed on the applicable Health Board formulary, but is a product which may be provided under MAS, the pharmacist may do so. This includes, wherever possible, prescribing on a generic basis. The supply of a medicine should be in response to a patient consultation and only when it is the most clinically appropriate intervention.

5.4 MAS is subject to the same prescribing support as other clinical services.

6. Administration and record keeping

6.2 The same MAS stationery must be used for each patient contact, recording whether they received a consultation, advice, a treatment or were referred to another health care professional.

6.3 Where appropriate, this information is to be annotated into the patient's medication record on the pharmacy patient medication record (PMR) system.

6.4 In the case of adverse reactions the pharmacist must consider whether there is a need to report any adverse drug reactions to the Committee on Safety of Medicines Scotland (CSM) through the Yellow Card reporting mechanism.

6.5 MAS stationery, for all interventions, including advice or referral, must be returned to Practitioner Services Division in accordance with the requirements set out in Schedule 3, paragraph 8 of the Directions.

Deadline for Submission of Registration Forms

6.6 MAS stationery for registration must be submitted within two months of the date of registration. The electronic message will be matched to the associated form and registrations may be cancelled if no form has been submitted within two months of registration.

6.7 Incomplete registration forms must not be submitted to Practitioner Services Division.

6.8 MAS providers must notify Practitioner Services Division when they enter registrations or activity by batch e.g. as a result of IT issues, and provide an estimate of registrations and consultations which have been delayed.

7. Remuneration

7.1 The MAS provider is remunerated for providing the MAS using a banded capitation fee.

7.2 The MAS provider is reimbursed for any product in line with the applicable formularies or prescribing policies. Section 7b of the Scottish Drug Tariff clarifies the pricing of certain items when prescribed generically.

Post Payment Verification

7.3 As with all pharmacy payments, MAS claims will be subject to scrutiny by Practitioner Services' Payment Verification (PV) team. Any anomalies or outliers will be investigated by PV and, where appropriate, will be referred to the Board and to NHS Scotland Counter Fraud Services (CFS).

7.4 MAS Providers who submit an unsatisfactory response to payment verification enquiries may be considered for onward referral.

7.5 Where after suitable investigation an NHS Board is satisfied that a MAS provider has not provided the services in accordance with the MAS Directions it can suspend payments for MAS and recover those made in respect of any appropriate period(s).

8. Training

8.1 A pharmacist providing the MAS must practise within their own competency.

8.2 It is the responsibility of the MAS provider to ensure that the pharmacy is able to offer the MAS Service as contracted at all times of opening. The MAS provider must ensure that all staff providing the service on their behalf e.g. locums have the competencies to deliver the service.

8.3 The pharmacist and MAS provider providing the service must be aware of and operate within the national service specifications and local formulary guidelines.

9. Information leaflets

9.1 National and local publicity initiatives and information leaflets prepared and/or approved by Scottish Ministers are used to raise public awareness of the service.