## Chief Medical Officer Directorate

Pharmacy and Medicines Division



**Dear Colleague** 

## ADDITIONAL PHARMACEUTICAL SERVICES PUBLIC HEALTH SERVICE – UPDATED SERVICE SPECIFICATION FOR COMMUNITY PHARMACY PROVISION OF PROPHYLACTIC ANTIPYRETIC (PARACETAMOL) FOLLOWING THE MENINGOCOCCAL GROUP B VACCINE; AND OTHER CHILDHOOD VACCINATIONS

## Summary

1. This Circular advises Health Boards and community pharmacy contractors of an updated service specification for the community pharmacy provision of prophylactic antipyretic (paracetamol) following the meningococcal group B vaccine; and other childhood vaccinations. It also provides supporting clinical guidance.

# Background

2. Directions for the Public Health Service enable community pharmacists to provide prophylactic antipyretic (paracetamol) following the meningococcal group B vaccine; and other childhood vaccinations. The current version is the Health Board Additional Pharmaceutical Services (Public Health Service) (Scotland) Directions 2023 ("2023 Directions").

3. NHS Circular <u>PCA(P(2015)25</u> issued on 28 September 2015, announced the introduction of prophylactic antipyretic (paracetamol) and enclosed the original service specification.

4. The clinical guideline on prophylactic antipyretic (paracetamol) has recently been revised which has led to the necessity to update the pharmacy service specification.

5. Fever is a common side-effect when infants are given the MenB vaccine with other routine childhood vaccines.

## 22 May 2025

Addresses

For action

Chief Executives, NHS Boards

For information

NHS Directors of Pharmacy

#### Enquiries to:

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6. The Joint Committee on Vaccination and Immunisation (JCVI) recommends that paracetamol should be given prophylactically when the MenB vaccination is given with the routine vaccines in infants under one year of age, to prevent or reduce fever. The JCVI statement about Meningococcal Group B disease and the Men B vaccine is available at <u>Meningococcal B vaccine: JCVI position statement - GOV.UK</u>

# Details

7. Documents attached to this circular are as follows:

- Annex A: Updated service specification for Meningitis B prophylactic paracetamol, including new clinical guidance as an Appendix.
- Annex B: Current 2023 Directions for the pharmacy Public Health Service.

8. The key change to the service specification is eligibility for using the pharmacy service. Due to updates to the clinical guidance, the pharmacy prophylactic paracetamol service will be available as off-label use to infants who meet specific criteria in terms of standard paracetamol dosing. This represents the vast majority of infants where pharmacy can provide a safe and appropriate service.

9. As indicated in the 2015 circular announcing the introduction of the pharmacy service, it does not replace existing GP practice responsibilities, but provides a complimentary service. In rural areas it may be more practicable for patients to access this from their GP practice. More vulnerable infants e.g. those with low weight or with existing health conditions, should be provided a prescription and remain under their care of their GP practice or specialist team. However, the majority of infants requiring prophylactic paracetamol will be eligible to do so via their local community pharmacy.

10. For infants who do not meet the updated eligibility criteria for the pharmacy service, health boards are responsible for ensuring arrangements are in place for them to receive a timely supply of prophylactic paracetamol following vaccinations.

# New clinical guidance

11. Clinical guidance has been produced for use by all pharmacy teams by Healthcare Improvement Scotland (HIS) in collaboration with Public Health Scotland (PHS) and the Scottish Neonatal and Paediatric Pharmacists Group (SNAPP). This guidance is not a Patient Group Direction (PGD) but is intended to give consistent guidance to pharmacists across Scotland. It is attached to the service specification at Annex A.

12. Some health boards may have local PGDs in place for Meningitis B prophylactic paracetamol. Where these are in operation, health boards should ensure they are communicated to community pharmacy contractors who should ensure their teams are aware of the local pathways.



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# Training

13. There is no specific e-learning module to be completed for this service but a paediatric module, giving information on childhood immunisations and prophylactic paracetamol, is available on NES Turas Learn: <u>Paediatric pharmacy : Childhood issues</u>.

# IT arrangements

14. Pharmacy teams should use the 'Men B supply' Universal Claim Framework (UCF) module to claim for each supply of Meningitis B prophylactic paracetamol. This supports accurate monitoring of service use and payments. **The Pharmacy First UCF module should not be used**.

15. Claims for prophylactic paracetamol should only be made where a supply has been undertaken as part of the NHS Community Pharmacy Public Health Service and not where a person is purchasing paracetamol for other indications.

16. Community Pharmacy Scotland has been consulted on the contents of this Circular.

# Action

17. Health Boards are asked to note and, where appropriate, act on the contents of this Circular and to bring it to the attention of community pharmacy contractors on their Pharmaceutical List, GPs, their Area Pharmaceutical Committee and colleagues involved in local arrangements for childhood vaccinations.

Yours sincerely

Alison Strath Chief Pharmaceutical Officer Pharmacy & Medicines Division



#### PROPHYLACTIC PARACETAMOL 120mg/5mL SUSPENSION PROVISION FOR THE PREVENTION AND TREATMENT OF FEVER POST IMMUNISATION AGAINST MENINGOCOCCAL GROUP B DISEASE

# Service Specification

# 1. Background

- 1.1 The Support for Meningitis B vaccination programme is part of the Public Health Service element of the community pharmacy contract.
- 1.2 This service specification should be read in conjunction with the attached Appendix providing clinical guidance for the supply of prophylactic paracetamol suspension for the prevention of post immunisation fever and also the Directions for the Public Health Service.
- 1.3 The routine childhood immunisation programme includes immunisation against meningococcal serogroup B disease (MenB) with the vaccine Bexsero®. The Joint Committee on Vaccination and Immunisation (JCVI) recommends that paracetamol should be given **prophylactically** when Bexsero® is given with the routine vaccines in infants under one year of age.

# 2. Service aim

2.1 To provide, where clinically indicated, a free supply of infant paracetamol oral suspension 120mg/5mL for prophylactic pyrexia relief in advance of or following childhood Meningococcal Group B (MenB) vaccination.

# 3. Service outline and standards

- 3.1 Infants under **one year of age** are eligible to receive this service from community pharmacies in advance of or after receiving Bexsero<sup>®</sup> vaccine.
- 3.2 The service must be delivered in person from a registered community pharmacy.

# 4. Service procedure

- 4.1 Before or post vaccination the parent/guardian will be advised to attend or present at their community pharmacy.
- 4.2 They should, where possible, provide confirmation of MenB vaccination by presenting the infant's 'Personal Child Health Record' booklet (the Red Book) or proof of appointment for vaccination to the pharmacy.
- 4.3 Pharmacists should check if the infant's weight is known (see eligibility criteria) and provide a supply or referral advice, as appropriate.



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- 4.4 A supply of infant paracetamol oral suspension 120mg/5mL and a 2.5 ml oral syringe should be provided to the parent/guardian. This is off-label use of paracetamol.
- 4.5 The pharmacist maintains a record for each supply and may be required to share information with appropriate parties in line with confidentiality protocols. Wherever possible the infant should be identified using their CHI number.
- 4.6The pharmacist ensures that the parent/guardian is counselled appropriately **on the use of prophylactic paracetamol and oral syringe.**
- 4.7 At the time of supply, the parent/guardian should be given verbal advice as set out in the attached *Appendix: Clinical guidance to be followed*.
- 4.8The service is provided according to any required regulatory and professional standards.
- 4.9 Any suspected adverse events should be reported using the MHRA Yellow Card Scheme.
- 4.10 Where a supply cannot be made, the parent/guardian should be advised of the reason and reassured that prophylactic paracetamol is available via other routes. Advice should be given that it is important that the infant still receives paracetamol, and to seek medical advice to access a supply on prescription from an appropriate prescriber, such as a GP, prescribing pharmacist or nurse in their GP practice, or children's immunisations teams.

# 5. Training/ resources

- 5.1 This service specification must be read alongside the Appendix providing clinical information.
- 5.2 All employed pharmacists, pharmacy technicians and locums should undertake, with certificate of completion, the six interactive e-learning modules on ADRs developed by NES and the Yellow Card Centre Scotland. Available on Turas at: <u>Adverse drug reactions (ADRs) | Turas | Learn (nhs.scot)</u>

## 6. Remuneration and Reimbursement

- 6.1 The pharmacist uses the 'Men B supply module' on the Universal Claim Framework (UCF) to claim for the service(s) they have provided.
- 6.2 Details of remuneration fees and reimbursement are set out in the Scottish Drug Tariff.



# Appendix: Clinical guidance to be followed by community pharmacists

#### **Product licence information**

Paracetamol 120mg/5mL (infant paracetamol suspension) is licensed for the relief of fever after vaccinations at 2, 3 and 4 months.

Bexsero vaccine is usually given at 8 weeks (2 months) and 16 weeks (4 months). From 1 July 2025, the offer of the second dose of MenB vaccine at 16 weeks of age will be brought forward to 12 weeks of age.

Paracetamol 120mg/5mL can be given prophylactically when Bexsero® is given with the routine vaccines in babies under **one year** of age. This is an off-label use.

#### Dosage

For babies meeting the eligibility criteria below, JCVI and PHS recommend a total of THREE doses of 60mg (2.5ml of the 120mg/5ml suspension) for the prevention of fever following Bexsero.

- Dose 1 should be given just before or immediately after the immunisation,
- Dose 2 should be given 4-6 hours after dose 1,
- Dose 3 should be given 4-6 hours after dose 2.

Further doses may be given if the baby is still pyrexial. Do not give more than 4 doses in any 24-hour period. If the baby is still pyrexial after 48 hours, then advice should be sought from a doctor or pharmacist

#### Who is eligible for supply under this service specification?

Babies must meet **all of the following eligibility criteria** to proceed with supply from community pharmacy:

- Baby is aged 2 months or older (note that in some cases a baby may appear to be 7 weeks and 6 days due to how the vaccination booking system calculates age. However these babies are still eligible).
- Current or most recent weight of baby known to be over 4kg.
- Baby was born at or after 32 weeks of gestation.

# If the above criteria are not met, parents/guardians should be referred to ensure supply (see below):

#### Who is ineligible for supply under this service specification?

- Baby has hypersensitivity to paracetamol or to any of the excipients listed in the relevant SPC.
- Baby is failing to thrive or is known to be under 4kg at their most recent recorded weight.
- Baby was born before 32 weeks of gestation.
- Baby is under investigation for or has a diagnosed underlying chronic condition that may affect the safety of paracetamol.

#### **Cautions:**

As per SPC.



# Who to refer parents to if pharmacy can't supply

• If a baby is not eligible, or if there is any uncertainty about the suitability of the baby to be given paracetamol, the parent/guardian should be encouraged to seek medical advice from an appropriate prescriber, such as a GP or a prescribing pharmacist/nurse. It should be clearly explained to the parent/guardian why a supply cannot be made. <u>The importance of obtaining a supply via an appropriate route should be emphasised to the parent/guardian.</u>

#### Advice to be given to parents/guardians

- You should always try and give the first dose of paracetamol just before or as soon as possible after the MenB vaccine.
- If your baby is sleeping when the next doses are due, don't wake them up. You can give it when the baby next wakes as long as there is at least 4 hours between each dose.
- If your baby is still having a fever (pyrexial) after 48 hours, then advice should be sought from a doctor or pharmacist.
- By the age of 12 months your baby's risk of fever after MenB vaccine is the same as with the other vaccines. So, your baby does not need to take 3 doses of paracetamol with their routine 12-month vaccinations. However, if your baby does get fever at home or appears to be in discomfort, you can give your baby infant paracetamol using the dosing schedule for a child of that age as outlined in the patient information leaflet.

# Relevant web links:

- Public Health Scotland. 2024. <u>What to expect after immunisation: Babies and children up to 5</u> years (publichealthscotland.scot) (Accessed 01/10/2024)
- BNF for Children: <u>Paracetamol | Drugs | BNFC | NICE</u> (Accessed 01/10/2024)
- UK Health Security Agency and Department of Health and Social Care. 2021. Immunisation against infectious disease "The Green Book": Chapter 22 Meningococcal, p 10. Available at: <u>Greenbook title page and index (publishing.service.gov.uk)</u> (Accessed 01/10/2024)
- SPC: <u>Paracetamol 120mg/5ml Oral Suspension (04917/0028)</u> Summary of Product <u>Characteristics (SmPC) - (emc)</u>
- General Medical Council: <u>Good Practice in Proposing, Prescribing, Providing and Managing</u> <u>Medicines and Devices – prescribing unlicensed medicines – professional standards 2021</u>
- Scottish Government 6 May 2025: CMO(2025)07 <u>Changes to the routine childhood vaccination</u> schedule and the selective neonatal hepatitis B vaccination programme from 1 July 2025



# NATIONAL HEALTH SERVICE (SCOTLAND) ACT 1978

# HEALTH BOARD ADDITIONAL PHARMACEUTICAL SERVICES (PUBLIC HEALTH SERVICE) (SCOTLAND) DIRECTIONS 2023

The Scottish Ministers give the following Directions in exercise of the powers conferred by sections 2(5), 27A, 27B, 28A and 105(7) of the National Health Service (Scotland) Act 1978<sup>1</sup>, and all other powers enabling them to do so.

#### 1. Citation and commencement

1.1 These Directions may be cited as the Health Board Additional Pharmaceutical Services (Public Health Service) (Scotland) Directions 2023 and come into force on 30 October 2023.

#### 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 2009<sup>2</sup>;

"Public Health Service" or "PHS" has the meaning ascribed in paragraph 3.1.

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



<sup>&</sup>lt;sup>1</sup> 1978 c.29; section 2(5) was amended by the National Health Service and Community Care Act 1990 (c.19), section 66(1); section 27A was inserted by the National Health Service (Primary Care) Act 1997 (c.46) ("the 1997 Act"), section 27(2); section 28A was substituted by the Health Act 1999 (c.8) ("the 1999 Act"), section 57, and amended by the Primary Medical Services (Scotland) Act 2004 (asp 1) ("the 2004 Act"), section 8, and schedule 1, paragraph 1; section 105(7) was amended by the Health Services Act 1980 (c.53), Schedule 6, paragraph 5(1) and Schedule 7, the Health and Social Services and Social Security Adjudications Act 1983 (c.41), Schedule 9, Part I, paragraph 24 and the 1999 Act, 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). <sup>2</sup> S.S.I. 2009/183.

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# **3.** Description of the Public Health Service

- 3.1 The Public Health Service (PHS) is a service that:
  - promotes the pro-active involvement of community pharmacists and their staff in supporting self-care,
  - offers suitable interventions to promote healthy lifestyles,
  - involves participating in national and local health campaigns,
  - provides a health promoting environment across the network of community pharmacies,
  - provides smoking cessation support which comprises advice and supply of smoking cessation products in order to help smokers successfully stop smoking,
  - provides sexual health support which comprises the supply of emergency hormonal contraception (EHC), bridging contraception and related advice,
  - provides prophylactic antipyretic (paracetamol) in advance of or following childhood meningitis B vaccination and other childhood vaccinations as clinically appropriate, and
  - supplies and, where necessary, administers naloxone for emergency use as clinically appropriate.
- 3.2 The component elements of PHS are specified in Schedule 1, paragraphs 1 and 2.

# 4. Health Board duty to arrange for a Public Health Service

4.1 Subject to paragraph 2 of Schedule 1 and until otherwise directed, Health Boards have a duty to arrange for the provision of a Public Health Service (PHS) for persons in their area as an additional pharmaceutical service.

## 5. Persons authorised to provide the Public Health Service

- 5.1 Health Boards may only enter into arrangements for the provision of PHS with:
  - (a) a person who is a registered pharmacist; or

(b) a person other than a registered pharmacist who, by virtue of section 69 of the Medicines Act 1968<sup>3</sup>, 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 is on the pharmaceutical list maintained by the Health Board in terms of regulation 5 of the 2009 Regulations<sup>4</sup>.

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



<sup>&</sup>lt;sup>3</sup> 1968 (c.67) section 69 was amended by the Pharmacy Act 1954 (c.61), Schedule 16, the Pharmacists (Fitness to Practise) Act 1997 (c.19), section 1 and Schedule paragraph 4, and the Statute Law Repeals Act 1993 (c.50), and by SI 2007/289.

<sup>&</sup>lt;sup>4</sup> Regulation 5 was amended by S.I. 1997/696, S.S.I. 1999/57, S.S.I. 2004/39, S.S.I. 2006/143, S.S.I. 2011/32 and S.S.I. 2014/148.

- 5.3 A pharmacist providing PHS in accordance with this paragraph must not be one who:
  - (a) has been disqualified under section 29B (2) of the Act;
  - (b) is suspended by direction of the Tribunal, or
  - (c) is the subject of a corresponding decision in England, Wales or Northern Ireland.

# 6. Compliance and Conditions

6.1 The arrangements made by a Health Board in accordance with paragraphs 4 and 5 shall include the terms and conditions specified in Schedules 1, 2 and 3, with which the provider of a PHS shall be obliged to comply.

# 7. Payment for the provision of a Public Health Service

- 7.1 Remuneration for the provision of a PHS will be paid at nationally negotiated rates as set out in the Drug Tariff and in accordance with Schedule 3 of these Directions.
- 7.2 The prices and methodology for calculating reimbursements to a PHS provider for any drugs, medicines or listed appliance that the provider may supply to patients in connection with providing PHS will be in accordance with the provisions set out in Part 1 of the Drug Tariff.

## 8. **Revocations**

8.1 These Directions revoke and supersede the Health Board Additional Pharmaceutical Services (Public Health Service) (Scotland) Directions 2015 and the Health Board Additional Pharmaceutical Services (Public Health Service) (Scotland) Amendment Directions 2021.

Signed by Alison Strath A member of staff of the Scottish Ministers

St Andrew's House, Edinburgh 8 September 2023



## NATIONAL HEALTH SERVICE (SCOTLAND) ACT 1978

#### HEALTH BOARD ADDITIONAL PHARMACEUTICAL SERVICES (PUBLIC HEALTH SERVICE) (SCOTLAND) DIRECTIONS 2023

#### **SCHEDULE 1**

#### SERVICES TO BE PROVIDED AS A PUBLIC HEALTH SERVICE

- 1. A Public Health Service (PHS) comprises the following services:
  - (a) the provision of advice to patients or members of the public on healthy living options and promotion of self-care in circumstances where in the professional opinion of the pharmacist it is appropriate to do so or by request from a patient or member of the public;
  - (b) making available for use by patients and members of the public a range of NHS or NHS approved health improvement campaign materials and other health improvement information and support material;
  - (c) participation in health improvement campaigns, each campaign being on display and visible within a pharmacy for a set period, determined nationally by Scottish Ministers following consultation with a body deemed to be representative of community pharmacy contractors;
  - (d) where agreed between a PHS provider and the Health Board, participation in locally agreed health improvement campaigns in the intervals between the national campaigns referred to under sub-paragraph (c);
  - (e) the provision of smoking cessation support comprising advice and supply of smoking cessation products as indicated in the service specification and NHS Board guidance, in order to help smokers successfully stop smoking;
  - (f) the provision of sexual health support comprising the supply of emergency hormonal contraception (EHC), bridging contraception and related advice;
  - (g) the provision of prophylactic antipyretic (paracetamol) in advance of or following childhood meningitis B vaccination and other childhood vaccinations as clinically appropriate; and
  - (h) the supply and, where necessary, administration of naloxone for emergency use as clinically appropriate.
- 2. Where a PHS provider decides not to supply emergency hormonal contraception (EHC) or bridging contraception according to subparagraph 1 (f) above, they should give notice in writing to the Health Board and advise the Agency of their decision and ensure prompt referral of patients to another provider who they have reason to believe provides that service.
- 3. For the provision of the services listed at subparagraphs 1 (c) and (d) a PHS provider shall make available space in a window of the pharmacy or, only in the absence of any suitable window, another space within the pharmacy. Such space should be made

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available for the full duration of the campaigns unless by agreement with the relevant Health Board because of unforeseen or special circumstances.



#### **SCHEDULE 2**

#### TERMS AND CONDITIONS OF THE PROVISION OF THE PUBLIC HEALTH SERVICE

- 1. For the purposes of PHS the 'patient medication record' is a pharmacy retained electronic record that as a minimum must include:
  - (aa) the patient's date of birth;
  - (a) the name and address of the patient;
  - (ba) the patient's sex;
  - (b) the patients' CHI number where available;
  - (c) name and address of the patient's GP practice;
  - (d) the dates of all dispensing episodes;
  - (e) the items dispensed.

#### **Provisions**

- 2. In providing the PHS service, PHS providers will be required to:
  - (a) use materials, including leaflets and posters, provided or approved by Scottish Ministers or Health Boards;
  - (b) use the display equipment, including display stands and other devices, made available by Scottish Ministers or Health Boards, which display equipment may not be used for any commercial purpose, and make appropriate space available within the pharmacy to hold such display equipment;
  - (c) undertake smoking cessation support, sexual health support, the provision of prophylactic antipyretic (paracetamol) in advance of or following childhood meningitis B vaccination and other childhood vaccination as clinically appropriate, and the supply and administration of naloxone for emergency use as clinically appropriate, as components of PHS in accordance with service specifications provided by Scottish Ministers.
- 3. In providing PHS a PHS provider and pharmacist must:
  - (a) have regard to and, where required, comply with, stated standards and administrative guidance that is from time to time produced by Scottish Ministers and disseminated by Health Boards to PHS providers as soon as possible after they are received;
  - (b) conform with the standards generally accepted by both the NHS and the pharmaceutical profession; and
  - (c) have completed the required training to enable them to offer patients requiring smoking cessation, sexual health and naloxone services.
- 4. In providing a PHS, a PHS provider is agreeing to the following:

- (a) that it takes responsibility for the veracity of any payment claims submitted to the Agency;
- (b) that its payment claims will be authenticated from appropriate records held by the provider or at the Agency;
- (c) that payments will be subject to Payment Verification and the PHS provider undertakes to co-operate fully with this process; and
- (d) that the PHS provider will provide documentary evidence to support payment claims.
- 5. The requirement for a complaints procedure under paragraphs 12 and 13 of Schedule 1 to the 2009 Regulations applies to the provision of a PHS.
- 6. The requirement for record keeping under paragraph 14 of Schedule 1 to the 2009 Regulations apply to the provision of a PHS.

#### **SCHEDULE 3**

#### PAYMENT FOR THE PUBLIC HEALTH SERVICE

- 1. The payments for providing the Public Health Service (PHS) are set out in the Drug Tariff.
- 2. Payments for providing the PHS under Schedule 1, Paragraph 1(d) will be at rates agreed between the NHS Board and the PHS providers.
- 3. Health Boards will be entitled to take such reasonable steps as are necessary to ensure that providers are:
  - (a) providing appropriate advice and support to patients and members of the public;
  - (b) making available a range of NHS or NHS approved health improvement campaign materials and information and support materials;
  - (c) displaying the agreed national campaigns, for the set periods;
  - (d) participating in locally agreed health improvement campaigns, where agreed with the Health Board; and
  - (e) providing the services and components named under Schedule 1.
- 4. Payments made to providers for providing a PHS will be subject to post payment verification checks and investigation by the Agency.
- 5. Where after suitable investigation a Health Board is satisfied that a PHS provider is not providing the services listed in Schedule 1 but is receiving payment under paragraph 1 of that Schedule and the Drug Tariff, it may (without prejudice to any other action which may be open to it):
  - (a) write to the provider advising of the conclusion reached by the investigation;
  - (b) inform the provider that the payments will be stopped with immediate effect; and
  - (c) recover any payments made to the provider in respect of any period(s) when the provider was not providing the services specified in Schedule 1.