Healthcare Quality & Strategy Directorate Pharmacy & Medicines Division

#### Community Pharmacy: Public Health Service Emergency Hormonal Contraception (EHC) Updated Directions and Service Specification

#### Summary

1. This circular advises of:

(i) the inclusion of ulipristal acetate alongside levonorgestrel within EHC service; and

(ii) the provision of prophylactic antipyretic (paracetamol) in advance of or following childhood meningitis B vaccination and other childhood vaccinations as clinically appropriate,

under the Public Health Service (PHS) available through community pharmacy.

## Background

2. NHS Circular PCA (P) (2008) 17 advised of Directions Additional Pharmaceutical for Services. including the provision of Emergency Hormonal Contraception (EHC) by means of the provision of levonorgestrel. Circular PCA (P) (2015) 2, subsequently advised of the issue of an updated PGD template covering the provision of the same drug.

#### Details

3. Ulipristal acetate has now been added as an alternative choice to levonorgestrel under PHS.

4. Ulipristal acetate may be provided to patients who present requesting emergency contraception for their own use within 120 hours of unprotected sexual intercourse (UPSI) or contraceptive failure. There is no requirement for a PGD for ulipristal acetate as it has been reclassified as a P medicine. A PGD remains in place for the supply of levonorgestrel.





#### 14 September 2015

Addresses

For action

Chief Executives, NHS Boards

For information

Chief Executive, NHS NSS

Director of Practitioner Services, NHS NSS

NHS Directors of Pharmacy

NHS Directors of Finance

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5. Pharmacists, when deciding on the most appropriate choice of therapy, should take account of both clinical need and local prescribing guidance as determined by their NHS Board Area and Drug Therapeutic Committee.

6. The availability of ulipristal acetate via PHS will take effect from **01 October 2015**. Pharmacists should ensure they provide the pharmacy (P) pack of ulipristal acetate for PHS and any outstanding POM packs should be used to dispense against GP10 prescriptions until supplies are exhausted. Likewise, pharmacists should continue to supply the POM pack of levonorgestrel against the PGD.

7. Further information will be issued shortly regarding the provision of prophylactic antipyretic (paracetamol) in advance of or following childhood meningitis B vaccination and other childhood vaccination as clinically appropriate.

8. Updated Directions including associated schedules in respect of the provision of the totality of Public Health Services provided as Additional Pharmaceutical Services are included at **Annex A**.

9. Pharmacists providing the service must complete the National Education for Scotland (NES) 'Contraception' e-learning resource as detailed in the updated service specification for the supply of EHC attached at **Annex B**.

10. Community Pharmacy Scotland has been consulted on the content of this circular.

# Action

11. NHS Boards are asked to;

- note the availability of ulipristal acetate via the extended PHS;
- copy this Circular to all community pharmacy contractors on their local lists; and
- copy this circular to Community Health Partnerships and the Area Pharmaceutical Committee for information.

Yours sincerely

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**Rose Marie Parr** Chief Pharmaceutical Officer Deputy Director Healthcare Quality & Strategy

ANNEX A

## NATIONAL HEALTH SERVICE (SCOTLAND) ACT 1978

## HEALTH BOARD ADDITIONAL PHARMACEUTICAL SERVICES (PUBLIC HEALTH SERVICE) (SCOTLAND) DIRECTIONS 2015

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 2015 and come into force on 1st October 2015.

#### 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

<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>&</sup>lt;sup>2</sup> S.S.I. 2009/183.

(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 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) and related advice, and
  - provides prophylactic antipyretic (paracetamol) in advance of or following childhood meningitis B vaccination and other childhood vaccinations 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  $1968^3$ , 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. The Health Board Additional Pharmaceutical Services (Public Health Service) (Scotland) Directions 2014

- 8.1 Subject to paragraph 8.2, these Directions revoke and supersede the Health Board Additional Pharmaceutical Services (Public Health Service) (Scotland) Directions 2014 ("the 2014 Directions").
- 8.2 Notwithstanding paragraph 8.1, the 2014 Directions shall continue to apply in respect of any PHS provided during the period from 4th July 2014 until 30th September 2015.

Signed by authority of the Scottish Ministers

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Dr Rose Marie Parr Scottish Government: A member of the Senior Civil Service

14<sup>th</sup> September 2015

## NATIONAL HEALTH SERVICE (SCOTLAND) ACT 1978

## HEALTH BOARD ADDITIONAL PHARMACEUTICAL SERVICES (PUBLIC HEALTH SERVICE) (SCOTLAND) DIRECTIONS 2015

#### **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) and related advice; and
  - (g) the provision of prophylactic antipyretic (paracetamol) in advance of or following childhood meningitis B vaccination and other childhood vaccinations as clinically appropriate.
- 2. Where a PHS provider decides not to supply emergency hormonal contraception (EHC) 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 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:
  - (a) the name and address of the patient;
  - (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 and the provision of prophylactic antipyretic (paracetamol) in advance of or following childhood meningitis B vaccination and other childhood vaccination 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 and sexual health 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.

# EMERGENCY HORMONAL CONTRACEPTION (EHC) SERVICE SERVICE SPECIFICATION

## PROVISION OF EMERGENCY HORMONAL CONTRACEPTION (EHC)

#### 1. Service aim

1.1 To provide, where clinically indicated, a free supply of emergency hormonal contraception (EHC).

#### 2. Service outline and standards

2.1 The service is available to any female client aged 13 years or over.

2.2 The service must be provided by the pharmacist in person.

2.3 The pharmacist takes a client history to ensure that they have sufficient information to assess the appropriateness of the supply.

2.4 Clients who are excluded from the service must be referred to other services for treatment and advice within the time frame for emergency contraception treatment to be effective.

2.5 The pharmacist supplies where clinically indicated, EHC recording the supply using the appropriate form and following the procedure set out in section 3. The pharmacist can supply:

- Levonorgestrel 1.5mg (POM), as a single dose as soon as possible after unprotected sexual intercourse (UPSI), according to a Patient Group Direction (PGD); or
- Ulipristal acetate 30mg (P) as a single dose as soon as possible but no later than 120 hours after UPSI.

2.6 The pharmacist should refer to guidance on first line therapy as determined by the local NHS Board Area Drug and Therapeutic Committee's prescribing formulary, taking into account clinical need.

2.7 The Pharmacist is responsible for ensuring that the service is userfriendly, non-judgemental, client-centred and confidential.

2.8 A pharmacist who chooses not to supply EHC on the grounds of religious, moral or ethical reasons must treat the matter sensitively and advise the client on an alternative local source of supply (another pharmacy, GP or sexual health service) available within the time frame for emergency hormonal contraception treatment to be effective (within 120 hours of unprotected sexual intercourse). (see RPS *Medicines, Ethics and Practice Guide*).

2.9 The service should be operated from premises that can provide an acceptable level of privacy to respect a client's right to confidentiality and safety.

2.10 The pharmacist must ensure maintenance of records for each supply and may be required to share information with appropriate parties in line with confidentiality protocols. Wherever possible clients should be identified using a CHI number.

2.11 The pharmacist must ensure, where appropriate, that the client is counselled on other sexual health matters and related topics, including long-acting contraception and sexually transmitted infections. Clients should be signposted to appropriate services where required. Written information should also be available on these topics.

2.12 The pharmacist must use their professional judgement to consider, and where appropriate, act on any child protection issues coming to their attention as a result of providing the service. This should be in line with local child protection procedures and any national or local guidance on under 16s sexual activity.

2.13 The service should be provided according to any required regulatory and professional standards.

## 3. Service Procedure

- 3.1 The pharmacist follows the procedure detailed below:
  - The pharmacist consults with female client, takes a client history and establishes the need, any possibility of current pregnancy, any contraindications, previous use and current medication to ensure the supply is safe and appropriate.
  - The supply is made and recorded in the patient medication record.
  - The client is counselled on the use of EHC and what to do if she vomits after taking the medication this includes returning to the pharmacy for a further supply if clinically appropriate.
  - The pharmacist advises that the next period may be early or late and to contact their GP or family planning adviser if the period has not occurred within 3 weeks or if menstruation is unusually heavy or light or if there is any presence of lower abdominal pain.
  - The pharmacist advises on the use of barrier contraception until the next period.
  - The pharmacist counsels the client on the importance of using regular contraception if they are sexually active and promotes the role of condoms in preventing sexually transmitted infections.

- The pharmacist provides the client with an EHC and contraception information leaflet to support any verbal advice.
- The pharmacist provides the client with written advice on local agencies who can provide access to further treatment and services if required, this includes details of specific services for young people under 18 years of age.
- The pharmacist provides any additional written and verbal advice on the risk of sexually transmitted infections as a result of unprotected sex and future contraceptive needs.

## 4. Training

4.1 Training on the supply of EHC should involve all pharmacy staff in order to ensure that everyone is aware of the key issues regarding the supply of EHC and so that all staff respond sensitively and appropriately to enquiries about EHC. In particular, staff should recognise that all requests for EHC should be referred to the pharmacist early on in the consultation.

4.2 Pharmacists providing the service must complete the NHS National Education for Scotland (NES) 'Contraception' e-learning resource which includes advice on ulipristal and a MCQ -assessment and the NES e-learning package on *Child Protection*. Both these resources are available on the NES Portal (<u>https://portal.scot.nhs.uk</u>). The training must be satisfactorily completed as per NES performance indicators by completing the appropriate assessments to a satisfactory standard. Pharmacists should have up to date knowledge of local sexual health services so that they can refer appropriately.