

SPECIFICATION

Service	Local Enhanced Service for the Provision of Emergency Hormonal Contraception (EHC) through Community Pharmacy
Council Lead	David Brady
Provider Lead	Pharmacist
Period	April 1 st 2021 – March 31 st 2022

1. Purpose

1.1 Introduction

The Service is to provide an Emergency Hormonal Contraception (EHC) Service, the dispensing of Levonorgestrel 1500 mcg tablet and Ulipristal 30mg tablet (see **Appendix 1** for PGDs) including the signposting / referral of Service Users into other local Sexual Health services and or General Practice.

Should the exclusion criteria for the PGD(s) apply, Pharmacists must take all practicable steps to provide the Service User with a same day referral appointment to their GP or the sexual health service.

Provision of free Dual Screen (chlamydia and gonorrhoea) kits for under 25-year olds (which attracts a payment – see Pricing page 15 and signposting / supply of free condoms can also be part of this Service. Please contact Gateshead Integrated Sexual Health Service

www.gatesheadsexualhealth.co.uk/, Telephone 0191 283 1577, or secure email inbox ststf.sexualhealthreferrals@nhs.net for further details.

National guidance on supplying emergency contraception during the COVID-19 pandemic can be found here www.fsrh.org/documents/fsrh-guidance-srh-services-second-wave-covid-october-2020/

The Service is to be delivered by accredited Community Pharmacists, free of charge to the Service User, according to the approved local Patient Group Directions (PGDs), the most recent versions effective from 1st April 2021 Direction Number GCP 2021/01C and GCP 2021/02C (**see Appendix 1**).

Pharmacists must record each consultation using Pharmoutcomes as it occurs (live service). All fields must be completed to ensure prompt payment.

Throughout this Specification, the term Pharmacist refers to pharmacists registered with the General Pharmaceutical Council to practice in Great Britain and providing the Service as employee/agent of the Provider.

1.2 Background

Sexual health is an important area of public health. The Government set out its ambitions for improving sexual health in its publication, *A Framework for Sexual Health Improvement in England*.¹

Sexual health needs vary according to factors such as age, gender, sexuality and ethnicity, and some groups are particularly at risk of poor sexual health, especially young people, Men who have sex with men (MSM) and BME groups. Strong links exist between deprivation and sexually transmitted infection (STI's), teenage conceptions and abortions.

From 1 April 2013 local government has been required by regulation to commission HIV Prevention, open access genitourinary medicine (GUM) and contraception and sexual health services (CASH) for all age groups. This includes services commissioned from general practice and pharmacy, such as long acting reversible contraception (LARC), Emergency Hormonal Contraception (EHC), including chlamydia screening.

1.3 Evidence Base (from latest available data <https://fingertips.phe.org.uk/>)

Equitable access to EHC is an important step in the drive to reduce teenage and unplanned pregnancies. The broad coverage that pharmacies offer ensures good geographical accessibility. Pharmacies must provide a confidential, and maintain, an anonymous service in an environment that respects the dignity and confidentiality of the Service User.

Teenage Conceptions (Under 18)

There has been a 60% reduction in Gateshead for under 18 conceptions since 1998, one of the most significant reductions in the North East region (source: Office for National Statistics).

In 2018, the under-18s conception rate per 1,000 females aged 15-17 years in Gateshead was 16.9, similar to the rate of 16.7 per 1,000 in England.

The decrease from 2017 was 27%. The rank within England for the under-18s conception rate was 75th highest (out of 149 UTLAs/UAs). Between 1998 and 2018, the decrease in the under-18s conception rate in Gateshead was 70%, compared to a 64% decrease in England.

Termination Rates

The abortion rate is increasing. In Gateshead the total number of abortions in 2019 was 642. The total abortion rate per 1,000 female population aged 15-44 years was 17.2, lower than the rate in England of 18.7 per 1,000. The rank (out of 149 UTLAs/UAs) within England for the total abortion rate was 94th highest.

Among the under-18 conceptions in Gateshead, the percentage of those leading to abortion in 2018 was 44.2%, similar to the percentage in England of 53.0%. The rank for the percentage of conceptions leading to abortion in Gateshead was 121st highest (out of 149 UTLAs/UAs). A lower than average percentage may indicate a higher proportion of young women choosing to continue the pregnancy, but can also reflect barriers to accessing abortion care.

¹ Department of Health (2013). *A Framework for Sexual Health Improvement in England*. (<http://www.dh.gov.uk/health/2013/03/sex-health-framework/>)

Repeat abortions are also increasing. In 2019, of Gateshead women aged under 25 who had an abortion, 28.7% had also had an abortion previously. This compares with 25.1% of women in the North East and 27.7% of women in England.

2. Service Scope

2.1 Service Description

The Provider must ensure when delivering the Service, that the various contraceptive protection and sexual health service options are discussed in conjunction with or without supplied medication. All women asking for emergency contraception must be told that a copper intrauterine device is more effective than an oral method (NICE Quality standard [QS129] and Faculty of Sexual and Reproductive Healthcare www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/). Free dual screening kits can also be supplied by the Provider to Service Users as well as signposting to free condom scheme providers. Please contact the Integrated Sexual Health Service to discuss this. www.gatesheadsexualhealth.co.uk

Requests to restock dual screen kits can be made to Dan Dobson at the Integrated Sexual Health Service by emailing stsft.sexualhealthreferrals@nhs.net or telephoning 0191 283 1577. The Provider will actively signpost to the Integrated Sexual Health Service to encourage full sexual health screening.

Should the exclusion criteria for the PGD(s) apply, Pharmacists must take all practicable steps to provide the Service User with a same day referral appointment to their GP or the sexual health service.

2.2 Aims and objectives of Service

The overall aim of the Service is to improve access to EHC for women aged 14yrs and above and to develop and enhance the EHC Service to contribute to reducing unplanned pregnancies and incidences of STIs.

The aims and intended outcomes of this Service are:

- To improve access to emergency contraception and sexual health advice.
- To increase the knowledge, especially among young people, of the availability of free emergency contraception from local pharmacies.
- To contribute to a reduction in the number of unintended pregnancies in the patient group.
- To increase the knowledge of risks associated with STIs relative to the type of contraception chosen.
- To signpost Service Users, especially those from high risk groups (Young people, BME), to available mainstream sexual health services.
- To contribute to the local network of contraceptive and sexual health services to help ensure easy and swift access to advice and services.

The objectives of this Service are to:

- Develop a network of community pharmacies offering an easily accessible, free emergency hormonal contraception to the patient group.
- Reduce health inequalities in sexual health
- Improve services, providing fast and convenient access and plurality of provision for Service User choice
- Provide advice on sexual health including onward signposting and referrals
- Increase referrals, particularly of higher risk groups, into mainstream sexual health services

3. Service Delivery

3.1 Service Model

All Providers shall provide a professional consultation service when assessing the Service User for emergency contraception.

- All women asking for emergency contraception are to be told that a copper intrauterine device is more effective than an oral method (NICE Quality standard [QS129] and Faculty of Sexual and Reproductive Healthcare www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/).
- The Provider is to ensure all reasonable efforts are made to refer the Service User on to their GP or the sexual health service and provide a follow up appointment to the Service User whilst they are present, should the PGD exclusion criteria apply.
- The Provider must assess the Service User's suitability for EHC in line with the requirements of this Service Specification and the current PGDs GCP 2021/01C and GCP 2021/02C) see Appendix 1.

If the consultation decision is to supply EHC, then this is to be made free of charge to the Service User.

Pharmacists must record each consultation using Pharmoutcomes. This must be carried out as a live service. All fields must be completed.

The Provider will provide support and advice to Service Users accessing the Service, including advice on the avoidance of pregnancy, STIs through safer sex and condom use. Information will also be given on the use of long acting reversible contraception along with other regular contraceptive methods including the provision of information on how to access free condoms, either supplied by the Pharmacy as part of the Condom Distribution Scheme or referral to the Integrated Sexual Health Service. Supply of a free Dual Screening kit to each patient under 25 years old is also encouraged with a £1 supplement paid to the Provider by the Council.

The Service is to be provided in compliance with Fraser guidelines and Department of Health guidance for the provision of confidential sexual health advice and treatment for young people aged under 16.

www.fpa.org.uk/factsheets/under-16s-consent-confidentiality

3.2 Care pathways

The Service standard or standard operating procedures set by the Provider must reflect national and local child and vulnerable adult safeguarding procedures.

A full guide to local arrangements can be found here:

www.gatesheadsafeguarding.org.uk/

Please refer to Appendix 2 for local safeguarding contacts

Whenever the exclusion criteria apply, or the Service User wishes to use the option of copper intra-uterine device for emergency contraception, the Provider must refer the Service User onto a specialist sexual health service www.gatesheadsexualhealth.co.uk/ or their GP if necessary. All practicable steps should be taken by the Provider to ensure the Service User is provided with a **same day referral** before they leave the consultation. It is recommended that Service Users requesting IUD as emergency contraception are also given EHC unless contraindicated. Providers are advised to keep an anonymous record of all these referrals.

When an accredited Pharmacist is not available to make a supply of EHC under the PGD, or in the event a supply cannot be made for whatever reason, the Service User is to be actively referred to or advised of alternative sources of supply, including other pharmacies that supply EHC under PGD and other local contraception and sexual health services, including General Practice. The Provider must telephone the referral to the service to which they are directing the Service User, to ensure that the service is available to the Service User that day and an appointment is confirmed and supplied to the Service User.

3.3 Interdependencies and relationships

The Provider will maintain efficient working relationships with allied services, agencies and stakeholders to enhance the quality of care delivered and ensure the holistic nature of the Service. Specifically, linkages are to be maintained with, GPs, the Integrated Sexual Health Service, wider Council services, and any other sexual health and secondary health service provider for use when relevant.

The Service cannot work in isolation and the Provider is required to work with partners to address the needs of Service Users and increase the opportunity for Service Users to achieve optimum sexual health outcomes. Partners will include:

- Abortion Providers
- Safeguarding Team
- Antenatal and post natal services
- Cervical Screening Programme
- Child and adolescent mental health services
- Drug, alcohol, obesity and smoking intervention services
- General practice
- Gynaecology
- HIV treatment and care services
- Male and female sterilisation services
- Mental health services
- Other healthcare service areas including voluntary sector
- Pathology and laboratory services

- Prisons and youth offender's institutions
- School and education services
- Sexual Assault Referral Centre
- Social Care
- Youth services

3.4 Relevant networks

The Provider is expected upon request to support programme developments across all Sexual Health Services in Gateshead

3.5 Communications

Posters advertising the Service must be made prominent on site. To download free advertising posters in relation to this Service provision for your premises please visit <http://archive.psnc.org.uk/data/files/publications/ThinkPharmacyPosters.pdf> The Provider will promote other local sexual health services and provide relevant written information in relation to the EHC service.

See also www.gatesheadsexualhealth.co.uk/ for Gateshead Integrated Sexual Health service, including clinic times and locations.

Other General health wellbeing websites with local information:

www.ourgateshead.org/oneyou

4. Service Location and Availability

4.1 Service location.

The Service is to be provided within the locality of Gateshead, within the full opening hours of the community pharmacy contract.

The Provider must have and use an accredited consultation area. The consultation area must:

- Enable both the Service User and the pharmacist to sit down together.
- Enable the Service User and pharmacist to talk at normal speaking volumes without being overhead by other visitors to the pharmacy, or by staff undertaking their normal duties.
- Be clearly designated as a private consultation area, distinct from the general public areas of the pharmacy.
- Have suitable equipment to enable live input of data into the EHC Pharmoutcomes template.

4.2 Equality, Accessibility, Acceptability

All policies and services, including those relating to sexual health, should be designed to meet the needs of the entire target population. This should include action to address inequalities, wherever relevant².

² Department of Health (2010). *Equality Impact Assessment for National Sexual Health Policy*

4.3 Referral process and access.

Service Users may self-refer or be referred via appropriate professionals from a range of organisations.

Following the consultation, whether medication is supplied, the accredited Pharmacist may decide it is relevant to provide onward signposting to sexual health services that provide long-term contraception methods and diagnosis and management of STIs.

Providers are to give guidance and signpost Service Users to community contraceptive services and GPs as appropriate.

Providers are to inform the Service User of other health and social care providers and support organisations, such as Service User groups, when appropriate.

If it is appropriate to supply EHC under the terms of the PGD, it is to be made free of charge to the Service User.

Service Users are to be actively referred to the local specialist sexual health website, to access clinic times, locations and the option to remotely request dual screening (chlamydia and gonorrhoea) testing kits. www.gatesheadsexualhealth.co.uk/

All medicines supplied must be labelled to comply with the Medicines Act 1968.

5. Training & Qualifications

5.1 Training & Qualifications

Please refer to Schedule 1 and the PGDs GCP 2021/01C and GCP 2021/02C: Qualifications/ Registration Requirements and Additional Requirements for a comprehensive description of requirements.

5.2 Patient Group Direction (PGD)

It is an absolute requirement under this Contract for the Provider to apply the PGDs GCP 2021/1C and GCP 2021/02C (Appendix 1). These will be downloadable via the LPC website and the Pharmoutcomes template module.

6. Contract Monitoring and Quality Framework

6.1 The Provider must complete **all fields** as appropriate within the Pharmoutcomes module template as a live service.

Other quality indicators that must be evidenced upon request:

- Women asking for emergency contraception are told that a copper intrauterine device is more effective than an oral method.
- The Provider actively advertising the Service within the Provider's premises, together with related sexual health information and the main sexual health service clinic

http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_111231.pdf

location and opening times which can be downloaded (see www.gatesheadsexualhealth.co.uk/)

- The Provider reviewing its Standard Operating Procedures (SOPs) and referral pathways for the Service on an annual basis
- The Provider ensuring that the Service is delivered within a private consultation area

6.2 A quality audit assessment can be arranged at any point within the Term of the Contract. To minimise the administrative burden, the Council would accept from Providers, (where applicable), existing quality audit information generated for the purposes of other principal stakeholders, for example NHS England (NHSE), General Pharmaceutical Council (GPhC), Care Quality Commission (CQC) etc.

The Council will endeavour to give the Provider 28 days' notice that it is carrying out the assessment, however if concerns or issues are raised regarding the Service, the Council can carry an unplanned assessment without any notice.

7. Performance Indicators

7.1 Performance of the Service is monitored by the completion of all required fields appropriate to the consultation via the PharmOutcomes platform.

7.2 The Provider will complete any national statistics as and when required. The Provider must supply information in relation to any other relevant Service outcome indicators requested by the Council.

7.3 It is essential that the Provider submits accurate performance indicator data using PharmOutcomes within agreed timescales. Training will be given on request.

Please see Schedule 2, KPIs

8. Pricing

Please see Schedule 3, Pricing

9. Special Circumstances and Conditions

n/a

Appendix 1 Gateshead EHC PGDs –

These are available to download via the Pharmoutcomes Gateshead EHC module and the LPC website <http://www.gandstlpc.net> 'services' tab

Appendix 2 – Local Safeguarding Arrangements

Comprehensive information and guides are available at
www.gatesheadsafeguarding.org.uk/

Gateshead Safeguarding Team Details Last update November 2019		
Integrated Referral & Assessment Team (IRT) (Children Services)	Civic Centre Gateshead	Office Hrs Tel No: 0191 433 2515/2653 R&ADuty@Gateshead.Gov.UK Out of Hours: 0191 4770844 EDT@Gateshead.Gov.UK Online referral form (child protection)
Safeguarding Unit	Gateshead Council	Gateshead Civic Centre Tel No: 0191 433 3565 SafeguardingChildrenUnit@Gateshead.Gov.UK
Dr Carmen Howey	Designated Doctor	Queen Elizabeth Hospital Tel No: 0191 445 6134 carmen.howey@nhs.net
Trina Holcroft	Designated Nurse, Safeguarding Children	Newcastle/Gateshead CCG, Riverside House Tel No: 0191 217 2552 Mob No: 07585403072 tholcroft@nhs.net
Ashleigh Miller	Named Nurse (safeguarding children)	Paediatric Department Queen Elizabeth Hospital Telephone: 0191 4452049 Safeguarding Admin: 0191 4452248 ashleigh.miller@nhs.net
Rachael Estrop	Named Nurse Child Protection	0-19 Service Gateshead Harrogate and District NHS Foundation Trust Tel: 07741700425 Rachael.estrop@nhs.net
Linda Hubbucks	Designated Nurse for Looked After Children	Tel: 0191 2172828 Mobile: 07769362016 Email: Linda.hubbucks@nhs.net
Dr A Liddle	Named GP (Children Protection)	Newcastle/Gateshead CCG alexander.liddle@nhs.net 07584 162366

SCHEDULE 1

CONDITIONS PRECEDENT

1. GPhC

Upon request, provide the Council with the General Pharmaceutical Council Registration Number for the Pharmacy premises along with details of a Pharmacy Superintendent and their GPhC Number.

2. Insurance

Upon request, provide the Council with a copy of the insurance policies to illustrate that the Required Insurances (as detailed in the Terms and Conditions and Invitation to Tender) are in place;

3. Training and Qualifications

3.1 **Accreditation is via annual CPPE Declaration of Competence for Emergency Hormonal Contraception. Final declaration remains the professional responsibility of the practitioner.**

It is recommended that the signed Declaration of Competence (DoC) required for this service is equivalent to the standards detailed within CPPE module Emergency Contraception www.cppe.ac.uk/programmes//ehc-e-03

Plus, practitioners MUST attend a local Gateshead workshop (delivered by Consultant in Sexual Health), covering local pathways and safeguarding arrangements. Date of attendance **MUST** be **within 2 years** of the consultation claim. Practitioners must take all practicable steps to attend these workshops or payments maybe withheld upon ongoing failure to do so.

3.2 Practitioners must meet and evidence upon request declared competencies for the purposes of audit and quality checks.

3.3 Providers must retain copies of their own or Staff's evidence of accreditation and training at the premises where they offer the Service and provide copies to the Council upon request. This remains an enrolled service. Ensure CPPE viewer is enabled to allow commissioners the option to audit competency status.

3.4 The Provider will be required to comply with General Pharmaceutical Council Standards of Conduct, Ethics and Performance and demonstrate maintenance of knowledge, skills and competencies, with evidence of Continuing Professional Development, ideally via the professional registration and revalidation process on the General Pharmaceutical Council website www.mygphc.org/home

- 3.5 Competency in the use of PGDs (see NICE competency framework for health professionals using patient group directions).
<https://www.nice.org.uk/guidance/mpg2/resources>
 - 3.6 The Provider shall ensure that each practitioner ensures their skills and knowledge are kept up to date prior to supplying under the PGD. Each practitioner supplying under the PGD should sign the Authorisation section of each PGD and that they accept personal responsibility for working under them, understand the legal implications and work within the scope of the PGD.
 - 3.7 Each practitioner must sign and date the current PGD and locums should sign the PGD for each shop they work in.
 - 3.8 The Provider must ensure that supporting Pharmacy Staff are trained in dealing with Service Users in a patient-centred, user-friendly, confidential and non-judgmental manner when requesting EHC. Providers are expected to work towards implementing the Department of Health paper 'You're Welcome' Quality Standards³.
 - 3.9 Pharmacists must with appropriate underpinning knowledge to competently undertake the clinical assessment of patients leading to treatment according to the indications listed in the accompanying PGDs.
 - 3.10 Each pharmacy must have a Standard Operating Procedure in place which covers the supply of Levonorgestrel 1500mg tablet(s) or a Ulipristal 30mg tablet via the PGDs.
4. **Patient Group Direction(s):** See above, Appendix 1

³ <https://www.gov.uk/government/publications/quality-criteria-for-young-people-friendly-health-services>

SCHEDULE 2**PERFORMANCE INDICATORS & SERVICE REQUIREMENTS**

Performance Indicators	Threshold	Method of Measurement	Consequence of breach
The Provider is making full use of the promotional material made available for the service and promotes its uptake via window displays or similar	100% compliance	- Contract Assurance process	Appropriate action under Clause 24 of the Terms and Conditions (<i>Defaults and Suspension</i>)
The Provider ensures that the Standard Operating Procedure (SOP) is in line with the Service Specification and reviews this SOP and the referral pathways for the Service on an annual basis.	100% compliance	- Contract Assurance process	As above
The Provider can demonstrate that Pharmacists and Staff involved in the provision of the Service have undertaken CPD and / or training relevant to this Service	100% compliance	- Accreditation criteria - Contract Assurance process	As above
Records kept regarding excluded Service Users, reasons for and subsequent actions or advice given.	100% compliance	- Contract Assurance process	As above
Records of all drugs supplied in relation to this Contract for audit purposes.	100% compliance	- Contract Assurance process	As above
Evidence of Fraser guidance fulfilled for under 16's.	100% compliance	- Contract Assurance process	As above
Evidence of counselling given, future contraception	100% compliance	- Contract Assurance process	As above

needs explored, STI testing undertaken, treatment (if necessary) and risk discussion and any details of onward referral			
Compliance with Pharmoutcomes database to input/monitor delivery of the Service (live input at point of consultation)	100% compliance	- Contract Assurance process	As above
All women asking for emergency contraception are told that a copper intrauterine device is more effective than an oral method (NICE Quality standard [QS129] Published date: September 2016 & FSRH Emergency contraception March 2017)	100 % compliance	- Contract Assurance process	As above

A quality audit assessment can be arranged at any point within the Term of the Contract. To minimise the administrative burden, the Council would accept from Providers, (where applicable), existing quality audit information generated for the purposes of other principal stakeholders, for example NHS England (NHSE), General Pharmaceutical Council (GPhC), Care Quality Commission (CQC). The Council will endeavour to give the Provider 28 days' notice that it is carrying out the assessment, however if concerns or issues are raised regarding the Service, the Council can carry an unplanned assessment without any notice.

SCHEDULE 3**PRICING**

In consideration of the Provider delivering the Service the Council will pay the Provider the following Price:

Element to be Delivered	Amount
Consultation	£11.26
Dual (chlam/gonorrh) screening kit	£1.00
Levonorgestrel per dose	£5.20 drug tariff unit price as of April 1 st 2021 plus VAT
Ulipristal per dose	£14.05 drug tariff unit price as of April 1 st 2021 plus VAT

The claims are to be submitted to the Council on a Monthly basis via Pharmoutcomes. The Council shall pay the Provider the Price following verification of the claim, within 30 days of submission of a valid claim form. Providers/Practitioners must include their full name next to each claim for consultation and/or supply of medication. The claim will only be paid so long as the Provider/practitioner complies with the PGD, 'Qualifications Required' and the inclusion criteria of the PGD. There is a 3-month grace period for submission and payment of historical claims. For the avoidance of doubt, any claim made outside of the 3-month grace period (claims for activity undertaken more than 3 months previously) will not be paid by the Council.

The Price shall remain as set out during the financial year 2021/2022. If the Contract is extended in accordance with Clause 2.4 of the Terms and Conditions the Price shall continue at the same rate unless a variation is agreed with Council.

SCHEDULE 4

DATA SHARING FOR EHC SERVICE

DEFINITIONS

Agreed Purposes: The performance by each party of its obligations under this Contract and in order to deliver the Service under the provisions of the National Health Service Act 2006 with the Localism Act 2011 providing the incidental powers to share data in order to allow for payment to be made for the provision of the Service.

Controller, data controller, processor, data processor, data subject, personal data, processing and appropriate technical and organisational measures: as set out in the Data Protection Legislation in force at the time.

Data Protection Legislation: (i) the Data Protection Act 1998, until the effective date of its repeal (ii) the General Data Protection Regulation ((EU) 2016/679) (**GDPR**) and any national implementing laws, regulations and secondary legislation, for so long as the GDPR is effective in the UK, and (iii) any successor legislation to the Data Protection Act 1998 and the GDPR, in particular the Data Protection Bill 2017-2019, once it becomes law.

Permitted Recipients: The parties to this agreement, the employees of each party, and the PharmOutcomes system.

Shared Personal Data: the personal data to be shared between the parties under clause 1.1 of this agreement. Shared Personal Data shall be confined to the following categories of information relevant to the following categories of data subject:

- a) Unique identifier for Service User
- b) Date of service provision to Service User
- c) Initials, age and postcode district of Service User
- d) Triage assessment of Service User (including referral or not, if so where from, reason for presentation to Service, alcohol involvement, time since UPSI, liver enzyme medication being taken, cycle length, last period date, point in cycle, period normal, other UPSI, breastfeeding, exclusion criteria applied, counselling given, previous use of EHC, EHC supplied or not, medicine batch number, expiry date, where taken, second dose required, chlamydia test and condoms supplied and any other relevant information); and
- e) Name of Provider and practitioner

1. DATA PROTECTION

1.1 **Shared Personal Data.** This clause sets out the framework for the sharing of personal data between the parties as data controllers. Each party acknowledges that one party (the Data Discloser) will regularly disclose to the other party (the Data Recipient) Shared Personal Data collected by the Data Discloser for the Agreed Purposes and shared via the PharmOutcomes system.

1.2 **Effect of non-compliance with Data Protection Legislation.** Each party shall comply with all the obligations imposed on a controller under the Data Protection Legislation, and any material breach of the Data Protection Legislation by one party shall, if not remedied within 30 days of written notice from the other party, give grounds to the other party to terminate this agreement with immediate effect.

1.3 **Particular obligations relating to data sharing.** Each party shall:

- (a) ensure that it has all necessary notices and consents in place to enable lawful transfer of the Shared Personal Data to the Permitted Recipients for the Agreed Purposes;
- (b) give full information to any data subject whose personal data may be processed under this agreement of the nature such processing. This includes giving notice that, on the termination of this agreement, personal data relating to them may be retained by or, as the case may be, transferred to one or more of the Permitted Recipients, their successors and assignees;
- (c) process the Shared Personal Data only for the Agreed Purposes;
- (d) not disclose or allow access to the Shared Personal Data to anyone other than the Permitted Recipients;
- (e) ensure that all Permitted Recipients are subject to written contractual obligations concerning the Shared Personal Data (including obligations of confidentiality) which are no less onerous than those imposed by this agreement;
- (f) ensure that it has in place appropriate technical and organisational measures, reviewed and approved by the other party, to protect against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data.
- (g) not transfer any personal data received from the Data Discloser outside the EEA unless the transferor:
 - (i) complies with the provisions of Articles 26 of the GDPR (in the event the third party is a joint controller); and

- (ii) ensures that (i) the transfer is to a country approved by the European Commission as providing adequate protection pursuant to Article 45 GDPR; (ii) there are appropriate safeguards in place pursuant to Article 46 GDPR; or (iii) one of the derogations for specific situations in Article 49 GDPR applies to the transfer.

1.4 **Mutual assistance.** Each party shall assist the other in complying with all applicable requirements of the Data Protection Legislation. In particular, each party shall:

- (a) consult with the other party about any notices given to data subjects in relation to the Shared Personal Data;
- (b) promptly inform the other party about the receipt of any data subject access request;
- (c) provide the other party with reasonable assistance in complying with any data subject access request;
- (d) not disclose or release any Shared Personal Data in response to a data subject access request without first consulting the other party wherever possible;
- (e) assist the other party, at the cost of the other party, in responding to any request from a data subject and in ensuring compliance with its obligations under the Data Protection Legislation with respect to security, breach notifications, impact assessments and consultations with supervisory authorities or regulators;
- (f) notify the other party without undue delay on becoming aware of any breach of the Data Protection Legislation;
- (g) at the written direction of the Data Discloser, delete or return and delete Shared Personal Data and copies thereof to the Data Discloser on termination of this agreement unless required by law to store the personal data;
- (h) use compatible technology for the processing of Shared Personal Data to ensure that there is no lack of accuracy resulting from personal data transfers;
- (i) maintain complete and accurate records and information to demonstrate its compliance with this Schedule 4 and allow for audits by the other party or the other party's designated auditor; and
- (j) provide the other party with contact details of at least one employee as point of contact and responsible manager for all issues arising out of the Data Protection Legislation, including the joint training of relevant staff, the procedures to be followed in the event of a data

security breach, and the regular review of the parties' compliance with the Data Protection Legislation.

- 1.5 **Indemnity.** Each party shall indemnify the other against all liabilities, costs, expenses, damages and losses (including but not limited to any direct, indirect or consequential losses, loss of profit, loss of reputation and all interest, penalties and legal costs (calculated on a full indemnity basis) and all other reasonable professional costs and expenses) suffered or incurred by the indemnified party arising out of or in connection with the breach of the Data Protection Legislation by the indemnifying party, its employees or agents, provided that the indemnified party gives to the indemnifier prompt notice of such claim, full information about the circumstances giving rise to it, reasonable assistance in dealing with the claim and sole authority to manage, defend and/or settle it. The liability of the indemnifying party under this clause shall be subject to the limits set out in 22 of the Terms and Conditions of this Contract.