

November 2017

Version 6.0

**Agreement between**

**The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the**

**United Kingdom**

**and**

**The Local Education Provider**

**in Pharmaceutical Medicine**

**Contents**

1. Introduction 3

1.1 Legal status of the LEP Agreement 3

2. Completing the LEP Agreement 4

2.1 Returning your completed LEP Agreement 4

3. LEP general information 5

3.1 LEP training locations 5

4. The role of the LEP 6

4.1 Supporting trainees 6 - 7

4.2 Supporting ESs 7

4.3 Supporting SAs 8

4.4 Documentary requirements and data sharing with the Faculty 8

4.5 Quality management and working with the Faculty 8 - 9

5. The role of the Faculty 10

6. Declaration and signatures 11 - 12

APPENDIX 1

LEP training sites 13

APPENDIX 2

The PMST curriculum and schedule of LEP

commitment to support training 14 - 20

APPENDIX 3

Data to be collected regarding ESs, AESs and trainees 21

APPENDIX 4

Quality management requirements 22

**1. Introduction**

The purpose of the ‘Local Education Provider (LEP) Agreement’ is to ensure that a pharmaceutical organisation (‘the organisation’) that is approved as a LEP to deliver the Pharmaceutical Medicine Specialty Training (PMST) programme can:

a) deliver the PMST programme for its trainees

b) fulfil the General Medical Council’s (GMC) mandatory standards for specialty training contained in *Promoting excellence: standards for medical education and training*, and

c) fulfil the GMC’s mandatory standards for recognising Educational Supervisors (ES) contained in *Recognising and Approving Trainers.*

The assigned Specialty Adviser (SA) will review the LEP Agreement for his or her LEP at the point of signature and on an annual basis, to confirm that the LEP is meeting the requirements. The Faculty of Pharmaceutical Medicine (‘the Faculty’), and the Pharmaceutical Medicine Virtual Deanery (‘the Virtual Deanery’) may share information contained in the organisation’s completed LEP Agreement with the GMC as part of its quality assurance responsibilities; some of this information might be made public in the Lead Postgraduate Dean’s report to the GMC.

Maintaining status as a LEP is held as a mark of quality for an organisation and a statement of its dedication to support PMST. This status may be declared in advertisements for hiring new physicians.

**1.1 Legal status of the LEP Agreement**

The LEP Agreement forms the basis of the agreement between the LEP and the Faculty, setting out the standards required to support PMST trainees and Educational Supervisors (ES), as well as the standards for interactions with the Faculty and compliance with quality management processes.

As such, by signing this agreement, the LEP agrees to abide by the conditions set out in the agreement. Failure to abide by these conditions may result in actions being taken, up to and including the removal of LEP status by the GMC.

**2. Completing the LEP Agreement**

The LEP Agreement must be completed by the personnel of the LEP, preferably the senior physician with responsibility for training or the human resources lead, in consultation with the medical director (if the medical director is not the relevant senior physician).

All sections of the agreement must be reviewed and the final signature page signed by the relevant individual as described.

## 2.1 Returning your completed LEP Agreement

Please return your completed LEP Agreementto:

Specialty Training Manager

Faculty of Pharmaceutical Medicine

19 Angel Gate

326a City Road

London

EC1V 2PT

Organisations are strongly advised to keep a copy of their completed LEP Agreement for their records.

**3. LEP general information**

|  |  |  |  |
| --- | --- | --- | --- |
| Name of organisation: | |  | |
| Name of site or business unit: | |  | |
| Type of organisation: | |  | |
| Is the organisation a designated body for revalidation? | |  | |
| Address: | | | |
|  | | | |
|  | | | Postcode: |
| Contact name: | | | Position held: |
| Tel: | Fax: | | E-mail: |
| Please include site address if different to above: | | | |

**3.1 LEP training locations**

Please list any additional training sites through which a trainee may rotate within the organisation in **Appendix 1**.

**4. The role of the LEP**

**4.1 Supporting trainees**

This section describes the responsibilities of the LEP to support its trainees. In signing this LEP Agreement, the LEP is confirming compliance with these standards.

* The duties, working hours and supervision of trainees are consistent with the delivery of high-quality, safe care of patients and subjects.
* There are clear procedures to address immediately any concerns about patient or subject safety arising from the trainee doctors.
* There are clear procedures to address immediately any concerns about, and to provide appropriate support to, trainee doctors in difficulty.
* Specialty training is quality controlled, reviewed and evaluated.
* Specialty training is fair and based on principles of equality and diversity.
* Processes for recruitment, selection and appointment are open, fair and effective.
* The educational facilities, infrastructure and leadership are adequate to deliver the curriculum.
* Trainees are supported to acquire the necessary skills and experience through induction, effective educational supervision, an appropriate workload, personal support and time to learn.
* Trainees can access and be free to attend regular, relevant, timetabled, organised educational sessions and training days, courses, resources and other learning opportunities of educational value to the trainee that form an intrinsic part of PMST, and have support to undertake this activity whenever possible.
* Education and training is planned and maintained through transparent processes which shows who is responsible at each stage.
* The organisation has available appropriate expertise to enable trainees to be assessed on all areas of the PMST curriculum to be completed at the work place.
* Trainees have access to meeting rooms, teaching accommodation and audiovisual aids.
* Trainees are enabled to develop and improve their pharmaceutical medicine and practical skills, through technology enhanced learning opportunities.
* The organisation has a system in place to ensure that trainees have regular feedback on their performance within each post.
* Trainees have, and are told the name and contact details of, a designated ES.
* Trainees sign a training/learning agreement at the start of their training.
* Trainees have a training log and/or a learning portfolio relevant to their current programme, which they discuss with their ES.

Please complete the content in **Appendix 2** to confirm the training support provided for each module of PMST.

**4.2 Supporting ESs**

This section describes the responsibilities of the LEP to support its ESs and Associate ESs (AES). In signing this LEP Agreement, the LEP is confirming compliance with these standards.

* There is a suitable ratio of ESs to trainees.
* ESs and AESs have adequate time for training identified in their job and development plans.
* ESs and AESs have adequate support and resources to undertake their training role.
* The organisation has a process in place, including an annual review, to ensure ESs and AESs are keeping up to date with the requirements for their role.
* There are clear procedures to address immediately any concerns about, and to provide appropriate support to, ESs in difficulty.
* ESs and AESs (or their representative) discuss with the trainee the educational framework and support systems in the post and the respective responsibilities of trainee and trainer for learning. This discussion includes the setting of aims and objectives that the trainee is expected to achieve in the post.
* ESs and AESs ensure that all involved in training and assessment of their designated trainees understand the requirements of the programme.
* Where an external ES or AES is required, the LEP will ensure appropriate standards and access are maintained as described above.
* If an external ES or AES is required, the LEP will negotiate, set or agree all fees directly with the external ES or AES for the performance of this service. On no account must the trainee be responsible for negotiating, setting or agreeing fees with the external ES or AES either directly or indirectly (e.g. via the trainee’s limited company if s/he is working as an independent pharmaceutical physician) for the performance of this service. On no account must the external ES or AES receive payment from the trainee either directly or indirectly (e.g. via the trainee’s limited company if s/he is working as an independent pharmaceutical physician) for the performance of this service.

**4.3 Supporting SAs**

This section describes the responsibilities of the LEP to support its SAs. In signing this LEP Agreement, the LEP is confirming compliance with these standards.

* LEPs provide a point of contact for the SA within the organisation.
* LEPs ensure that SAs have access to ESs and trainees, facilitating the organisation of meetings as required.
* LEPs ensure access to documentation as required by SAs.

**4.4 Documentary requirements and data sharing with the Faculty**

* The LEP considers the PMST programme at board level or equivalent (this may be the medical director or person responsible for approving PMST in the organisation) i.e. it has an executive or non-executive director at board or equivalent level (as defined above), responsible for supporting the delivery of PMST, setting out responsibilities and accountabilities for training and for producing processes to address under performance in postgraduate training. This consideration is documented.
* The LEP has documented clear accountability, a description of roles and responsibilities, and adequate resources available to those involved in administering and managing training.
* The LEP will complete the LEP Agreement and notify the Faculty of any relevant changes to its content subsequently, including changes to any of the content of the Appendices.
* The LEP has a system in place to document data required by the Faculty to demonstrate compliance with GMC requirements to support specialty training (see **Appendix 3**) and is able to share these data in real time.

**4.5 Quality management and working with the Faculty**

This section describes the expectations of the LEP in respect of working with the Faculty and within the Faculty quality management (QM) systems.

* The LEP will comply with systems and process to ensure robust QM in alignment with the Faculty and the GMC standards for specialty training.
* This includes, but is not limited to, systems and processes for documenting the required data capture, provision of support to specialty trainees, ESs and AESs, sharing of data with the Faculty and inspection by external groups such as the Faculty or GMC (see **Appendix 4**).
* This also includes responding to findings in a timely and effective manner to ensure standards of specialty training are met and maintained.
* A right of appeal for LEPs applies as per the Faculty QM process.

**5. The role of the Faculty**

This section describes the general principles of responsibilities of the Faculty in relation to LEPs, ESs and trainees. Detailed content regarding specific processes and procedures are captured in Faculty documentation and Appendices to this agreement.

With respect to this agreement and specialty training, the Faculty will:

* Ensure that the LEP agreement form and its content are aligned to GMC requirements.
* Provide trainees with sources of impartial help, advice, guidance and support, and promote the maximum response to all national training surveys conducted by the GMC.
* Manage systems and processes to recognise ESs, using criteria consistent with the GMC’s standards and requirements.
* Quality manage the training arrangements at LEPs, aligned to GMC’s standards.
* Ensure that systems and structures enable each LEP to contribute to the delivery, maintenance and development of specialty training.
* Keep appropriate records and report information to the GMC regarding training and ESs, according to statutory requirements.
* Cooperate with quality assurance by the GMC.

**6. Declaration and signatures**

|  |
| --- |
| **To be completed by the personnel of the LEP, preferably the senior physician with responsibility for training or the human resources lead, in consultation with the medical director (if the medical director is not the relevant senior physician).**    *“This organisation supports the delivery of the PMST programme as defined in the Specialty Training Curriculum for Pharmaceutical Medicine August 2010 (Amended 2014), and in accordance with the GMC’s standards for specialty training.”*    Name:  Job title:  Correspondence address:  Tel:  E-mail address:  Signed: Date:  **To be completed by the Specialty Adviser**  *“I confirm that I am responsible for the quality management of the PMST programme on behalf of the Pharmaceutical Medicine Virtual Deanery. Within this organisation, the programme complies with the GMC’s standards.”*  Name:  Correspondence address:  Tel:  E-mail address:  Signed: Date: |

|  |
| --- |
| **To be completed by the Chair of the Specialist Advisory Committee on Pharmaceutical Medicine or the Director of Education & Training**  *“In my opinion the organisation is fit to deliver the PMST programme in accordance with the Specialty Training Curriculum for Pharmaceutical Medicine August 2010 (Amended 2014) and the GMC’s standards for specialty training.”*  Name:  Signed: Date:  **To be completed by the Lead Postgraduate Dean**  *“This application has the support of the Lead Postgraduate Dean and the Pharmaceutical Medicine Virtual Deanery.”*  Name:  Signed: Date: |

**APPENDIX 1 – LEP training sites**

|  |
| --- |
| **Please give training locations within the organisation through which trainees may rotate** |
| 1. |
| 2. |
| 3. |
| 4. |
| 5. |
| 6. |

On behalf of the organisation:

Signed: Date:

**APPENDIX 2 – The PMST curriculum and schedule of LEP commitment to support training**

**It is important to refer to the detailed curriculum document before completing all parts of this section.**

Key: IWE – In-Work Experience

EMC – External Module Course

ITC – Item Taught Course (e.g. short course, in-house or external)

*We confirm that the total training opportunities available within the organisation are as indicated (NB: Please complete one column only per item):*

**Medicines Regulation (RGN)**

**Module Item Description Please tick as appropriate**

RGN 1 Legislative frame work for the  IWE |  EMC |  ITC

development and registration

of medicines

RGN 2 Post-authorisation safety  IWE |  EMC |  ITC

monitoring and regulatory

reporting procedures

RGN 3 Product safety update reports  IWE |  EMC |  ITC

RGN 4 Unlicensed medicines  IWE |  EMC |  ITC

RGN 5 Marketing Authorisation  IWE |  EMC |  ITC

RGN 6 Clinical trials and global  IWE |  EMC |  ITC

drug development

RGN 7 Wider availability of medicines  IWE |  EMC |  ITC

and product deregulation

RGN 8 Product defects, counterfeit  IWE |  EMC |  ITC

products, miscellaneous

procedures and other

requirements

**Clinical Pharmacology (CLP)**

**Module Item Description Please tick as appropriate**

CLP 1 Non-clinical pharmacology  IWE |  EMC |  ITC

and toxicology

CLP 2 Literature review and preparation  IWE |  EMC |  ITC

of manuscripts for publication

CLP 3 Clinical pharmacology and  IWE |  EMC |  ITC

toxicology evidence required

in regulatory approval process

CLP4 Design, execution and analysis  IWE |  EMC |  ITC

of earl-phase studies in man

CLP 5 Ethical principles and practices  IWE |  EMC |  ITC

in clinical research with volunteer

subjects

CLP 6 Good Clinical Practice (GCP) in  IWE |  EMC |  ITC

clinical pharmacology

CLP 7 Clinical pharmacology of new  IWE |  EMC |  ITC

medicine within the clinical

development plan

CLP 8 Application of therapeutic area  IWE |  EMC |  ITC

knowledge to identify unmet

therapeutic needs

**Statistics and Data Management (SDM)**

**Module Item Description Please tick as appropriate**

SDM 1 Statistical principles in design  IWE |  EMC |  ITC

of clinical studies

SDM 2 Clinical input and review of  IWE |  EMC |  ITC

Statistical Analysis Plan (SAP)

SDM 3 Statistical principles, methods for  IWE |  EMC |  ITC

analysis and presentation of data

from clinical studies

SDM 4 Statistical principles for the design,  IWE |  EMC |  ITC

conduct, analysis and reporting of

clinical, post-marketing and health

economic studies

SDM 5 Statistical methods used and  IWE |  EMC |  ITC

presented in reports and

publications

SDM 6 Case Report Form (CRF) design  IWE |  EMC |  ITC

and clinical data management,

including CDISC, Electronic Data

Capture and MedDRA

**Clinical Development (CLD)**

**Module Item Description Please tick as appropriate**

CLD 1 Disease area analysis within  IWE |  EMC |  ITC

Industry clinical development

environment

CLD 2 Evaluation of non-clinical and  IWE |  EMC |  ITC

Phase I data for CDP for a new

drug

CLD 3 End-points used in clinical trials  IWE |  EMC |  ITC

CLD 4 Clinical Development Plan (CDP)  IWE |  EMC |  ITC

CLD 5 Development of clinical trials  IWE |  EMC |  ITC

protocol

CLD 6 Regulatory and ethical aspects  IWE |  EMC |  ITC

of clinical development

CLD 7 Management and conduct of  IWE |  EMC |  ITC

clinical trials

CLD 8 Evaluation of all suspected  IWE |  EMC |  ITC

adverse events in clinical trials

CLD 9 Clinical study reports and  IWE |  EMC |  ITC

manuscripts prepared for

publication

**Healthcare Marketplace (HMP)**

**Module Item Description Please tick as appropriate**

HMP 1 Healthcare environment and  IWE |  EMC |  ITC

pharmaceutical medicine

(‘The External Environment’)

HMP 2 Medical-marketing  IWE |  EMC |  ITC

communications with legal

and regulatory compliance

HMP 3 Pharmaceutical industry;  IWE |  EMC |  ITC

structure, function, stakeholders,

commercial drivers and impact of

these business elements on broader

healthcare market

(‘The Internal Environment’)

HMP 4 Commercial analysis of product  IWE |  EMC |  ITC

potential within industry business

environment

HMP 5 Competitor environment  IWE |  EMC |  ITC

HMP 6 Interface of pharmaceutical  IWE |  EMC |  ITC

industry with broader healthcare

environment

**Drug Safety Surveillance (DSS)**

**Module Item Description Please tick as appropriate**

DSS 1 Regulatory requirements for  IWE |  EMC |  ITC

pharmacovigilance (PV)

and their historical background

DSS 2 Medical assessments and drug  IWE |  EMC |  ITC

safety reporting

DSS 3 Spontaneous reporting  IWE |  EMC |  ITC

and signal detection

methodologies and medical

evaluation of ADRs for causality

assessment

DSS 4 Evaluation of risk/benefit balance  IWE |  EMC |  ITC

and the Risk Management Plan

(RMP)

DSS 5 Regulatory actions to address  IWE |  EMC |  ITC

patient safety

DSS 6 Communications of safety issues  IWE |  EMC |  ITC

DSS 7 Issues and crisis management  IWE |  EMC |  ITC

DSS 8 Progress, major advances and  IWE |  EMC |  ITC

future challenges in drug

safety and PV

**Interpersonal, Management and Leadership Skills (IML)**

**Module Item Description Please tick as appropriate**

IML 1 The managed environment  IWE |  EMC |  ITC

in which pharmaceutical

medicine operates

IML 2 Principles and practices of  IWE |  EMC |  ITC

people management and

leadership

IML 3 Interpersonal and communication  IWE |  EMC |  ITC

skills in pharmaceutical medicine

IML 4 Communicating the knowledge,  IWE |  EMC |  ITC

skills and behaviours of competent

pharmaceutical medicine

**APPENDIX 3 – Data to be collected regarding ESs, AESs and Trainees**

The LEP has a system in place to capture the following data and a mechanism in place to share these data in real time (which may include requiring the Trainee or ES to capture and share these data with the Faculty):

* The number of Trainees currently working in the organisation, their names, GMC number, start date in the organisation, current role, leaving date and any issues relating to concerns relevant to Good Medical Practice (GMP) 2013.
* The number of ESs and AESs currently working in the organisation, their names, GMC number, start date in the organisation, current role, leaving date and any issues relating to concerns relevant to GMP 2013.
* Qualifications of ESs and AESs, dates of initial training for the ES or AES role, dates of ongoing updates to training, dates of review of performance and approval to continue in role.
* A statement from the SA on whether, or not, all ESs and AESs are providing adequate and appropriate educational supervision.

On request, ES appraisal forms should be provided for purposes of audit.

On behalf of the organisation:

Signed: Date:

**APPENDIX 4 – Quality management requirements**

This appendix describes the Faculty Quality Management processes and the LEP’s responsibilities in respect of these.

* The LEP should have a system to document feedback from trainees regarding their ESs and AESs, and information from ES and AES appraisals, including information on relevant training and CPD.

On behalf of the organisation:

Signed: Date: