

Review of training in Pharmaceutical Medicine

Introduction

We set the standards and requirements for the delivery of all stages of medical education and training. [*Promoting excellence: standards for medical education and training*](#) sets out ten standards that we expect organisations responsible for educating and training doctors in training in the UK to meet.

Our Quality Assurance Framework defines how these organisations should work together to meet our standards. Each year, we undertake a number of quality assurance visits and reviews to check and monitor the delivery of medical education and training in order to ensure our standards are being met.

Small specialty reviews are carried for those specialties where there are fewer than 250 doctors in training. We know that delivery of training in smaller specialties poses a number of challenges; however, there is often limited information or evidence available to indicate areas of concern or highlight examples of good practice. This is mainly due to the low number of doctors training within any one local education provider (LEP) and we will not publish national training survey results for any LEP where there are fewer than three doctors in training. For smaller specialties this significantly affects the information and evidence available.

Our aim in conducting this small specialty review is to gain a better insight into the quality management systems that govern Pharmaceutical Medicine Specialty Training (PMST). We want to build on the limited information that we do have in order to assure us, doctors in training, educators, and associated stakeholders that the quality of training meets the standards expected. This review focuses on the quality management policies, processes and systems in place that support PMST.

Background

The PMST small specialty review took place in the spring of 2018. As part of this review, we met with the Lead Dean, the Faculty of Pharmaceutical Medicine, and other representatives from the Pharmaceutical Medicine Virtual Deanery (PMVD), which conducts the day-to-day business of PMST. The PMVD consists of a number of stakeholder

organisations (see page 3) which together are responsible for the management and oversight of the specialty training - this is different from the quality management of other specialty training programmes by Health Education England or postgraduate deaneries.

We visited a number of sites that deliver training, where we met with specialty advisers (SAs), educational supervisors (ESs) and doctors in training. We received written input from four individuals unable to attend visits on the day.

Evidence available to inform a visit of this type is limited, but includes data from the following sources:

- The national training survey (NTS)
- Annual Review of Competence Progression (ARCP)

A previous visit to review training in the specialty was undertaken by the Postgraduate Medical Education & Training Board (PMETB) in December 2009, before PMETB merged with the GMC in 2010. This visit report was taken into account by the visitors ahead of this review.

Pharmaceutical Medicine

PMST is a competency-based four-year programme. The programme provides doctors in training with a wide breadth of knowledge in key areas of the pharmaceutical industry. The structure of each training programme is bespoke to the individual and comprises a mixture of in-house training and external training courses. Employing organisations fall into three main categories – pharmaceutical companies, independent contract research organisations (CROs) and medicine regulatory authorities. Doctors in training may also work as an independent practitioner within any of these organisations. As with any specialty, the in-house training opportunities available will depend on the type and size of employing organisation.

The PMST programme consists of seven modules, six of which cover the themes required to pass the knowledge-based exam:

- Medicines Regulation (RGN)
- Clinical Pharmacology (CLP)
- Statistics and Data Management (SDM)
- Clinical Development (CLD)
- Healthcare Marketplace (HMP)
- Drug Safety Surveillance (DSS)
- Interpersonal, Management and Leadership (IML)

As the name suggests, the last module listed (IML) covers a broader generic skill set in which doctors in training demonstrate and acquire competencies expected of a practising pharmaceutical physician. At least two modules plus the IML must be completed in the

workplace. The remaining modules can be completed in the workplace, via approved training courses or a mixture of the two.

The Pharmaceutical Medicine Specialist Advisory Committee (PM-SAC) approves courses for PMST. At the time of writing this report there are three approved course providers – Drug Safety Research Unit (courses relevant to module DSS), King's College London (courses relevant to modules CLD, CLP, HMP and RGN) and RK Statistics Ltd (one course relevant to module SDM).

The PMST knowledge-based examination is the Diploma in Pharmaceutical Medicine (DPM). The DPM is a two-part examination comprising a multiple choice paper, a short answer question paper and a critical appraisal paper. Acquisition of the DPM is a prerequisite for the award of Certificate of Completion of Training (CCT) or Certificate of Eligibility for Specialist Registration (CESR).

It should be noted that PMST is not mandatory and physicians are able to progress a career within the pharmaceutical industry without pursuing a CCT in the specialty.

The Pharmaceutical Medicine Virtual Deanery

As the vast majority of PMST is undertaken outwith the NHS and the usual specialty training management structures, quality management of the programme is undertaken by an entity known as the Pharmaceutical Medicine Virtual Deanery (PMVD), a collaborative multi-stakeholder non-legal entity.

The PMVD is comprised of:

- The Faculty of Pharmaceutical Medicine (FPM)
- The Lead Postgraduate Dean
- The Joint Royal Colleges of Physicians Training Board (JRCPTB) which includes the Pharmaceutical Medicine Specialty Advisory Committee (PM-SAC)
- The Pharmaceutical Medicine Virtual Deanery 'staff', which is comprised of the Faculty and the JRCPTB and conducts the day-to-day business. PMST business is reported regularly through the PM-SAC.

The Lead Dean

Postgraduate deans are responsible for the strategic overview and operational delivery of postgraduate medical training. Each postgraduate dean is responsible for one or more specialties at a national level. At the time of the review, the Lead Dean for Pharmaceutical Medicine was Dr Andrew Frankel, Postgraduate Dean for Health Education South London. Dr Frankel demitted in April 2018 and is replaced by Professor Geeta Menon.

Local education providers (LEPs)

The GMC is responsible for approving training programmes and training sites. This process is undertaken in collaboration with a number of organisations who collectively are responsible for checking, and continuing to check, that the training environment meets the standards set out in *Promoting excellence*. At the time of writing this report, there are in excess of 100 local education providers (LEPs) approved for training in PMST.

The PMVD requires organisations that support PMST to sign a LEP agreement with the Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom. This document details our standards that must be met with regard to specialty training as well as those governing the recognition and approval of trainers. The agreement also details how each module of the PMST training programme will be delivered – whether by in-work experience, external modular course or item taught course. Once completed, the signed agreement document is reviewed by the Specialty Adviser (SA) and then passed on to the PMVD to seek formal approval of the training location from us. The PMVD requires SAs to review learning agreements on an annual basis.

Appointment to the specialty

Doctors training in PMST are already employed within the pharmaceutical industry. Recruitment to PMST is open to those who fulfil the eligibility criteria. There is an expectation by the PMVD, as detailed in the LEP agreement, that processes for recruitment, selection and appointment meet our standards and are open, fair and effective.

We are aware that the PMVD has been working with our approvals team to enhance the description of entry requirements for PMST to include details of the competencies and examples of the evidence to be provided on application. We would encourage the FPM to continue to work with approvals in a timely manner to ensure that selection processes to enter PMST are sufficiently evidence-based and robust.

Summary of findings

1. It is clear from those we met that doctors training in PMST are self-motivated, dedicated individuals who are keen to progress their careers in the pharmaceutical industry and promote the benefits of the specialty. Whether speaking with doctors in training, educational supervisors (ESs) or SAs we heard many examples of colleagues working together to advance the specialty and improve the education and training experience.
2. We heard that, in the main, doctors feel well supported by their ES, and much praise was also given to the information, advice and support provided by the FPM Specialty Training Manager. The structure of the training programme is such that, for any one organisation, it is entirely feasible for there to be only one or a very

small number of doctors training in PMST at any one time. The visit team highlighted the need for accessible policies and guidance in order to mitigate the risks associated with over-reliance on the advice provided by any one person.

3. As each training programme is bespoke to the individual, many of the doctors in training we met had received excellent training, undertaken in a supportive environment, rich in opportunities to gain experience and acquire competencies. There are examples of ESs seeking out training opportunities and liaising with colleagues such that, where feasible, specialty training could be undertaken in-house. However, unfortunately, this is not always the case. Some doctors in training we spoke to described situations in which their employing organisation had little knowledge or understanding of the PMST curriculum, or the bespoke training programme that had been agreed.
4. As such, some individuals spoke of difficulties setting time aside for training and a lack of in-house training opportunities. Where in-house training opportunities are not available, doctors in training are required to undertake external courses and we heard that, where these are self-funded, the cost of such courses can be prohibitive. The cost is further exacerbated by the fact that doctors in training are only permitted to undertake courses approved by the FPM, with only one course being approved for each theme of the training programme. The FPM undertakes ongoing approval of courses to ensure that the content matches the requirements of the curriculum. The findings of the most recent NTS suggested the greatest barriers to training in PMST are workload, lack of formal teaching and lack of exposure to competencies required.
5. We heard that the PMVD has, in the past, undertaken work to evaluate attrition rates from the specialty but that unfortunately, due to the number of variables, it had not been possible to draw any meaningful conclusion from this analysis.
6. Whilst a CCT in PM is not required for career advancement within the industry, some organisations advertise the fact they support PMST training in order to attract high calibre applicants.
7. Going forward, the PMVD must review quality management arrangements to ensure there are processes in place and evidence to show that LEPs are meeting standards and that, as far as possible, doctors in training have parity with regard to the training experience and support available to them, regardless of the type of organisation in which they are employed.

Areas working well

We generally note good practice where we have found exceptional or innovative examples of work or problem-solving related to our standards that should be shared with others and/or developed further.

Number	Paragraph in <i>Promoting Excellence</i>	Areas working well
1	R1.1	The standards and processes around safety are clearly understood and embedded and involve doctors in training (paragraph 8).
2	R2.15	In the main, the doctors in training we met felt well supported by their educational supervisor (paragraph 2).
3	R4.1	The educational supervisors we met had all received an induction to their role (paragraph 24).

Requirements

We set requirements where we have found that our standards are not being met. Our requirements focus on what an organisation has to address to make sure that it meets those standards. We will monitor activity against these requirements until we are satisfied that our standards are met. The expectation is that all of the organisations that comprise the PMVD, working in a coordinated way, will take action to meet the following requirements.

Number	Paragraph in <i>Promoting Excellence</i>	Requirements for the PMVD
1	R2.1	Quality management processes must be strengthened with a view to obtaining evidence and information that informs the quality of education and training, and ensures equity in the training experience. The PMVD must be able to show that LEPs are meeting the standards for the quality of medical education and training and responding appropriately to concerns (paragraphs 15, 40 to 46).
2	R2.1	The role and responsibilities of specialty advisers must be communicated to all those involved in training so that their programme management and quality management functions are clearly understood (paragraph 35-39).

3	R2.16	The Pharmaceutical Medicine Virtual Deanery must develop and communicate clear guidance on the recognition and support of doctors in difficulty (paragraph 54-58).
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Recommendations

We set recommendations where we have found areas for improvement related to our standards. Our recommendations explain what an organisation should address to improve in these areas in line with best practice. We will monitor activity against these recommendations to ensure improvements take place. The expectation is that all of the organisations that comprise the PMVD, working in a coordinated way, will take action to meet the following recommendations.

Number	Paragraph in <i>Promoting Excellence</i>	Recommendations for the PMVD
1	R2.1	The PMVD should develop easily accessible documentation to mitigate the risk currently associated with the reliance on specific individuals (paragraphs 2, 9 & 57).
2	R5.11	The ARCP process should be clarified so that it is clear to all that the process meets the requirements of the Gold Guide, where the decision is made on the evidence in the e-portfolio and prior to the doctor's face-to-face meeting with the panel (paragraph 30-34).
3	R4.4/R4.5	The work that has already been started to support and develop established trainers should be continued (paragraph 24-29).

Findings

Patient safety and raising concerns

- Doctors in training told us that the pharmaceutical industry is tightly regulated and places great emphasis on patient safety. Throughout the development and lifespan of a medicine this is achieved through pharmacovigilance, whilst day to day activities are structured using standard operating procedures. Those we met were fully aware of the requirement to contribute and comply with systems to protect

patients in order to meet both our and industry standards, and knew how to raise concerns within the organisations in which they were employed.

9. The LEP learning agreement requires organisations to have processes and procedures in place to address patient safety concerns, and the PMVD documentation outlines a number of ways in which doctors in training can raise a concern about education and training e.g. via the Annual Review of Competence Progression (ARCP), directly with their ES or SA and through the Faculty of Pharmaceutical Medicine Trainees' Committee. Doctors in training were aware of the different routes for raising concerns but told us that, in the main, they would raise any issues they had directly with their ES or with the FPM Specialty Training Manager.
10. We heard that in situations where concerns are raised by an external organisation, such as a breach in the Association of the British Pharmaceutical Industry Code of Practice, steps are taken by the employing organisation to investigate and promote learning from mistakes. However, the doctors in training, ESs and SAs we spoke to were unsure whether such incidents should formally be brought to the attention of the PMVD. Depending on the nature of the concern, and those involved, this could have implications in terms of the support offered to any doctor training within the organisation and in the suitability of the employing organisation as a LEP (see section on Quality Management).

Bullying and undermining

11. No bullying and undermining concerns were raised with us during this review.

Recruitment and selection

12. Doctors training in PMST are already employed within the pharmaceutical industry and as such the PMVD has no input with regard to their initial appointment. We heard that employing organisations often require applicants to undergo a selection process during which skills relevant to the position are assessed. In contrast, recruitment to PMST is open to all those who fulfil the eligibility criteria.
13. In the main, the doctors in training we met considered employing organisations to be supportive of those pursuing PMST. This supports the findings of the 2017 NTS in which over three-quarters of respondents agreed that organisations value higher medical training for physicians. In organisations where there are large numbers of doctors training in the specialty and approved educational supervisors, we heard of informal support groups being formed that provide much needed information and guidance. Unfortunately, for many of the smaller organisations such networks do not exist, leaving doctors in training and their educational supervisors somewhat isolated.

Out of Programme

14. Within the pharmaceutical industry, employees often change employer. Where a new employing organisation is not approved for training, a doctor in training may be required to undertake a period out of programme (out of programme career break - OOPC). This allows arrangements to be put in place either to approve the training location and/or to identify a suitable ES.
15. We heard that doctors in training are permitted to undertake a period of training overseas, but that different out of programme training (OOPT) processes are applied depending on whether the training location is within or outside of the EEA. We will work with the PMVD to ensure that the quality management of this process is clarified and consistently applied.

Educational supervision

16. The PMVD recognises two supervisory roles - ES and associate ES (AES). AESs differ from ESs in that they do not hold a medical qualification and are not permitted by the PMVD to sign off training competencies. ESs and AESs are formally appointed by the PMVD against set criteria, with applications to the position being reviewed and confirmed by the PM-SAC or a designated member.
17. When applying to undertake PMST, it is the responsibility of the doctor in training to identify an ES within the employing organisation. Where, for whatever reason this is not possible, the PMVD may offer assistance by proposing an ES employed by a different organisation or an independent pharmaceutical physician willing to perform the role.
18. We heard that when doctors in training move to a new employer they sometimes retain their existing ES until a new ES has been appointed. Appointment of a new ES can sometimes be delayed if the nominated individual has yet to undergo training for the role. Due to commercial sensitivities, doctors in training that move between employing organisations may be required to redact information from evidence uploaded into the e-Portfolio as evidence of attainment of competencies.
19. It was noted that for reasons of confidentiality, smaller organisations may not support the engagement of an external ES. In such circumstances, and where supervision is provided by an AES, it may fall to the SA to sign off competencies. The PMVD are gathering information to determine the extent of the issue such that they can develop appropriate guidance and avoid conflict of interests.
20. There is no requirement that an ES must have completed PMST themselves or have prior knowledge of the training programme. The PMVD does not limit the number of doctors in training assigned to each ES; however, the PMVD suggest the average number to be two.

- 21.** In contrast to requirements set out in the LEP agreement, we heard little evidence to suggest that ESs have dedicated time set aside within their job plans for educational purposes. It is clear, both from the conversations with doctors in training and their supervisors, that time for training is at a premium and many of those we spoke to talked of having to schedule time well in advance to discuss training requirements and achieve competency sign-off. Such time pressures are often exacerbated ahead of ARCPs. PMVD guidance suggests that ESs and doctors in training should formally meet approximately every three to four months and this was consistent with what we heard during the visit.
- 22.** For many of the doctors in training we spoke to, their ES was also their line manager. Both parties told us that this arrangement works well as the line manager then has a greater awareness of the demands associated with PMST, can help plan training time around work commitments and can help seek out and facilitate in-house training opportunities.
- 23.** Unlike their peers, ESs from outside the employing organisation may be disadvantaged by not fully appreciating the training opportunities available within the local education provider. Furthermore, and as many of the training opportunities are arranged via professional internal networks, they may be unable to influence access to the training opportunities that do exist.

Support for trainers

- 24.** The ESs we met had all received an induction to the role and considered the information they had received to be satisfactory. Introductory sessions are held three times a year with refresher training for ESs taking place every three years.
- 25.** For a number of years the FPM has held an annual education day. Whilst this event was originally intended for doctors in training, ESs and SAs, more recently FPM members and those with an interest in pharmaceutical medicine education and training are also invited to attend. As such some agenda items, whilst still of interest, may not always be directly applicable to the PMST programme. The PMVD told us that attendance to this event is not compulsory and is not monitored with regard to those associated with PMST.
- 26.** We heard that within some of the larger organisations, informal support networks exist whereby ESs swap ideas or seek guidance and support from each other. Whilst such groups are commendable, we are concerned that inadequate support is available to ESs working in isolation or in organisations in which there are few doctors in training. This issue was raised in the PMETB visit to the specialty in 2009 and since then the SAC has considered how to address the issue. One solution has been to provide a 'top tips' section of the FPM website. At the time of writing this report, top tips have been written covering topics such as PMST planning, the e-

portfolio, ARCP preparation and other information. Whilst undeniably useful, these documents provide high level guidance and are not directed specifically towards the needs of ESs, some of whom may have no, or very little, prior knowledge of the requirements of the training programme.

- 27.** Other than training undertaken as part of their induction, ESs receive no further training unless a specific need is identified. We heard that the performance of the ES can often be deduced from discussions that take place during the ARCP – for example, if inadequate evidence has been presented to support sign off of competencies or if evidence has been uploaded to the e-Portfolio in an untimely manner. It is unclear how such observations feed into the quality management or appraisal process.
- 28.** Where ESs revalidate through the Faculty of Pharmaceutical Medicine, the annual appraisal provides an opportunity to review educational responsibilities and monitor compliance with standards. Where ESs undertake revalidation through a designated body other than the Faculty of Pharmaceutical Medicine, appraisal of the educational role is incorporated into general professional appraisal. In this situation the appraiser may not be fully aware of the standards to be met. We heard that the PMVD is considering how best to review ES performance in a way that would allow incorporation into appraisal evidence, but that it has yet to be decided what this will entail.
- 29.** From information reviewed ahead of the visits and comments heard on the day, it is unclear whether the PMVD has considered the specific training needs of those ESs who have not undertaken PMST themselves, those working in isolation or who are employed by an organisation different to that of the doctor or doctors in training they supervise.

Annual Review of Competence Progression (ARCP)

- 30.** The Gold Guide provides a framework to support the day to day management of postgraduate specialty training and ensures consistency in decision-making by Postgraduate Deans.
- 31.** Specific guidance is included within the Gold Guide with regard to the ARCP, both in terms of the process itself and the composition of the ARCP panel. The Gold Guide states that doctors in training are not required to meet with the ARCP Panel whilst evidence is being considered and the outcome decided. Where an unsatisfactory outcome is indicated, a doctor in training may be required to meet with the ARCP panel or senior educator once the evidence has been reviewed, to discuss the reason for the unsatisfactory outcome and to discuss further focused or remedial training. In contrast, the PMVD requires all doctors enrolled in PMST to attend the ARCP and many do so accompanied by their ES.

- 32.** Doctors in training and their ES described a process whereby the ARCP Panel is provided with access to the training e-Portfolio a number of weeks ahead of the ARCP date. We heard that, on the day of the ARCP, doctors in training are required by the panel to present or discuss a topic of their choice, based on evidence in their e-Portfolio, and then answer questions on the subject. The panel then makes suggestions with regard to areas that have worked well or that require improvement. A discussion also takes place between all those present about plans for training in the following year. Doctors in training told us that following these discussions they were usually presented with their ARCP outcome - the perception of the majority of trainees being that their presentation to the panel and ensuing discussion had contributed to the ARCP outcome. Many of those we met considered the ARCP to be a rigorous process, and whilst it was obvious that doctors in training felt re-assured having their ES present, the visit team questioned the presence of the ES in the process.
- 33.** It would seem that two processes are being performed under the umbrella term 'ARCP' – a review of training undertaken over the past twelve months and a discussion of training planned for the forthcoming year. It is not clear to all doctors training in PMST and their ES that ARCP outcomes are decided ahead of face-to-face meetings and that ensuing discussions do not inform the final outcome except where further information is required. Furthermore, it is unclear if or how topics of discussion and proffered solutions are fed back into the quality management process.
- 34.** When asked, the PMVD confirmed that the training portfolio is reviewed ahead of any meeting with the doctors in training and that the ARCP outcome is agreed at that time. We heard that any subsequent conversations are to provide guidance or direction. The Lead Dean advised the only exception to this being where further information or clarification is required. In such circumstances, and following initial discussions, the doctor in training and their ES will be asked to leave the room whilst the panel re-considers the evidence available to them.

Specialty Advisers (SA)

- 35.** The SA role is a joint appointment of the Faculty of Pharmaceutical Medicine and the Lead Postgraduate Dean. SAs receive no remuneration for work undertaken on behalf of the PMVD.
- 36.** The SAs we met were enthusiastic proponents of the specialty and clearly enjoy their role. The relationship between the SA, LEP, doctor in training and their supervisor is pivotal to the quality management process and we heard that this starts as soon as a doctor in training expresses a wish to embark on specialty training. It is the responsibility of the SA to meet with the LEP signatory to agree the outline of the training programme and to declare, in the first instance, the suitability of the local education provider to deliver PMST.

- 37.** It is apparent that SAs have extensive experience within the pharmaceutical industry and we heard how they use this experience and support from within their own professional networks to help them in their role. We heard that SAs work closely with doctors in training, supervisors and LEP contacts to address training issues. As such, and in order to be effective, each SA must develop and foster excellent working relationships with all those involved in the delivery of PMST.
- 38.** Throughout the course of the review it became apparent that, due to a lack of formal governance structures and the fact that, in the main, SAs work independently there is some variability in how the role is performed. Further details of this and the implications for the quality management process are described below.
- 39.** Ahead of the visit we reviewed the person specification against which SAs are appointed. The first essential criteria states that the SA should be registered with a licence to practise with us as the regulator. In documentation reviewed ahead of the visit, we noted the PMVD are aware of SAs continuing in the role despite no longer having a licence to practise and have discussed possible transitional solutions, but that no succession planning has been finalised.

Quality management

- 40.** In accordance with our quality assurance framework, the PMVD is responsible for the quality management of PMST.
- 41.** Whilst the PMVD has overall responsibility for the quality management of specialty training, we heard that much of the day-to-day work has been delegated to the SA. In part, this is due to lack of resources (both in terms of time and money), making it impractical for the PMVD to directly quality manage over 100 LEPs. Secondly, the PMVD considers that the SA is best placed to address any concerns with respect to training as they work closely with LEPs, doctors in training and their supervisors. The PMVD confirmed that SAs perform both a quality and programme management role.
- 42.** The PMVD governance document states that SAs will typically communicate with doctors in training and their ESs once or twice a year and this coincides with what we heard during the review. We were told that no formal record is made of routine interactions.
- 43.** In documentation reviewed ahead of the visit, we noted that the SA is also responsible for undertaking an annual review of each LEP they oversee. Whilst this is written in the SA role specification and is also a requirement of the LEP agreement, we did not see or hear any evidence to suggest a formal review of each LEP is being undertaken to assess the suitability of the training environment.

Furthermore, we heard there is no obligation for the SA or PMVD to be notified of any regulatory sanctions imposed on organisations where training takes place, the result being that such information is not taken into consideration when reviewing the LEP.

- 44.** The Deanery Executive Group (DEG) comprising the Lead Dean, SAC Chair and the FPM Director of Education and Training discusses concerns raised with respect to LEPs and decides the best course of action. When serious concerns are identified a triggered visit process is initiated. Level one of the process involves the identification of a concern, which is then followed by a visit where the SA meets with the doctor/s in training, ES/s and LEP personnel. The SA is required to report their findings back to the DEG who decide whether the issue can be rectified locally using an action plan. Level two of the process is initiated for more serious concerns and involves a formal site visit by two senior members of PMVD personnel. Level three is a referral directly to us and is for matters relating to patient or trainee safety or trainee fitness to practise.
- 45.** We reviewed two level 1 visit reports, both of which related to concerns that had been identified via the NTS. There was inconsistency in the way the process was recorded with only one being recorded on a triggered review report template. Furthermore, in one instance the SA had agreed the action plan ahead of the report being reviewed by the DEG (although it was confirmed that the Lead Dean was in agreement with the proposed course of action).
- 46.** With SAs playing such an important part of the quality management process, formal arrangements must be put in place describing the remit and scope of their role. Furthermore, whilst it is accepted that SAs must be allowed a degree of autonomy, arrangements must be put in place to standardise the information that is collected and reported back to the PMVD. In doing so, the PMVD will be better placed to collate evidence and information that supports the quality of education and training across such a broad range of training environments.

Programme management

- 47.** We heard mixed accounts with regard to the training arrangements agreed between each doctor in training and their employing organisation. Whilst some doctors in training had negotiated time available for training and/or financial support to help with the cost of external courses and had a formal learning agreement with their employer, many others didn't. It is unclear whether such disparity impacts on learning outcomes but is an issue that warrants further consideration.
- 48.** The comments we heard are supported by the results of the 2017 NTS which showed that an appreciable number of respondents did not receive leave or expenses from their employer to attend meetings and/or did not receive financial

support towards PMST training. Throughout the course of the review, doctors in training told us that those employed within CROs undergo a very different specialty training experience to those employed by the larger pharmaceutical companies. This is due, in part, to the limited in-house training available. Furthermore, we heard that many CROs are unable to bear the cost of external courses meaning that their employees must fund the costs themselves. Depending on the number of courses undertaken, this can extend into thousands of pounds.

Data Collection

- 49.** Ahead of the visit we saw evidence that the PMVD reviews NTS results and reports findings back to the SAC. As mentioned previously, we will only publish results where there are more than three doctors training in any one location and often this means that detailed results are only available for the larger pharmaceutical companies. From documentation reviewed ahead of the visit we saw that the PMVD presents NTS results to the SAC either by specialty, thereby averaging results across all organisations or by individual organisation where the number of doctors training is equal to or more than three. In the latter instance, this meant that detailed responses were only presented to the SAC for nine LEPs.
- 50.** Aside from the generic questions asked of all doctors in training, the NTS also contains a number of specialty-specific questions written by the PMVD. We saw no evidence to suggest that responses to these questions are being analysed or used to inform PMVD business and improve training.
- 51.** Furthermore, whilst we saw evidence that some analysis is undertaken of exam results for the Diploma in Pharmaceutical Medicine, this extended only to doctors training in PMST who had passed or failed the examination on the first attempt or re-sit.
- 52.** Finally no evidence was supplied by the PMVD to suggest that they had undertaken formal analysis of progression data using ARCP outcomes, although we did hear that outcomes were discussed at SAC meetings.
- 53.** Throughout the course of the review, we repeatedly heard that the quality of training differed significantly depending on the type of employing organisation. The PMVD advised us that they have not tried to analyse data according to employer type, as variation between organisations makes comparisons difficult. Variation across training providers is not limited to PMST and quality management processes must be reviewed with a view to obtaining evidence and information that supports the quality of education and training, and ensures equity in the training experience across LEPs.

Supporting doctors in difficulty

54. The PMVD places the onus for supporting doctors in difficulty on the local education provider, the ES and SA.
55. The LEP agreement states that the LEP should have 'clear procedures in place to address immediately any concerns about and to provide appropriate support to, trainee doctors in difficulty'. We did not see any evidence to suggest that the SA or PMVD through the quality management process check whether such procedures are in place and, if so, that these are adequate.
56. During the induction workshop, ESs are provided with a 'Rapid Diagnostic Framework' - an algorithm developed to inform the best course of action to help a doctor in difficulty. One such option is to refer the doctor in training to support mechanisms within the employing organisation such as Occupational Health. It was of interest that the approach adopted by some ESs was of that for an employee in difficulty rather than a learner in difficulty, although it is recognised that the two can and may be interconnected.
57. During the course of the review, we did hear mention of referral to in-house support programmes but it is apparent that the type and level of support is likely to differ between organisations. We also heard reference to ESs seeking external courses on the subject. More often than not those we spoke to suggested that ESs seek informal advice from other ESs, the SA or the FPM Specialty Training Manager. Furthermore, it is apparent from the discussions we had with ESs, that where formal and informal interventions do take place these may not always be recorded or reported back to the PMVD.
58. Organisations must have processes for identifying concerns about a learner's health, well-being and educational progression, and for sharing information between relevant organisations.

Time for learning

59. Pharmaceutical Medicine training is undertaken alongside employment within the pharmaceutical industry. As might be expected, doctors in training described periods of peak activity during which it is difficult to identify time for training combined with less intense periods of work.
60. Many of those we met emphasised the need to plan training in order to maximise in-work opportunities such that competencies can be identified and signed off in accordance with curriculum requirements. Similarly, where work commitments allow, we heard that doctors in training use this time to schedule external training courses or to update their training portfolios in preparation for the annual review of competency progression. In the majority of cases doctors in training we met were

of the opinion that it is the responsibility of individuals, in conjunction with their ES, to plan their training and ensure that there is time for learning.

- 61.** Where the ES and line manager is one and the same person the issue or workload doesn't appear to be problematic and time for learning can be scheduled around work commitments. Some of those we spoke to suggested that employing organisations are not always fully conversant with the demands of PMST and we heard examples of ESs having to liaise directly with line managers to negotiate time for training.
- 62.** The LEP agreement states that it is the responsibility of LEPs to support trainee access to educational sessions, training days and courses; however, we heard from some doctors in training that this was not always the case. Some of the doctors in training we spoke to had been required to take annual leave in order to attend training courses. The 2017 NTS results show that whilst the majority of those asked said that they had been able to attend specialist society meetings, nearly a third had not. Of those that had attended, nearly a fifth did not receive leave from their employer to do so. Furthermore, nearly a quarter of those who responded consider workload to be a barrier to training.

Acknowledgement

We would like to thank the Pharmaceutical Medicine Virtual Deanery, the Lead Dean and all the people we met during the review for their cooperation and willingness to share their learning and experiences. We would also like to thank those organisations that agreed to host meetings on our behalf.

Appendix 1: Visit details

Visit team

Team leader	Dr Barry Lewis
Visitor	Dr Phil Ambery
Visitor	Dr Niten Vig
Visitor	Dr Kim Walker
GMC staff	Kim Archer, Jane MacPherson

Visit Dates

05 February 2018: Meeting with Pharmaceutical Medicine Virtual Deanery

28 February 2018: Meeting with Specialty Advisers, Educational Supervisors & Doctors in Training (Meeting hosted by FPM)

01 March 2018: Meeting with Educational Supervisors & Doctors in Training (Meeting hosted by Boehringer Ingelheim, Bracknell)

01 March 2018: Meeting with Educational Supervisors & Doctors in Training (Meeting hosted by GSK, Brentford)

13 April 2018: Meeting with Educational Supervisors & Doctors in Training (Meeting hosted by Sanofi, Guildford)

13 April 2018: Meeting with Pharmaceutical Medicine Virtual Deanery (Meeting hosted FPM)