



Comhairle na nDochtúirí Leighis
Medical Council

Accreditation of Postgraduate Training Bodies Under Part 10 of the Medical Practitioners Act 2007

Report on the Accreditation of The Programme of Specialist Training in Pharmaceutical Medicine

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Statement with regard to the Freedom of Information Acts, 1997 and 2003

The Medical Council currently makes information routinely available to the public in relation to its functions and activities and, in line with that practice, a summary of this report will be available on the Council's website, www.medicalcouncil.ie in due course.

The Freedom of Information Act is designed to allow public access to information held by public bodies which is not routinely available through other sources and access to this document may be sought in accordance with that Act. The Medical Council complies fully with the terms of the Freedom of Information Act. It should be noted that access to information under the Freedom of Information Act is subject to certain exemptions and one or more of those exemptions may apply in relation to some or all of this report.

A. Preface

1. Context of the Accreditation Session

The Medical Council Accreditation Team met with the Irish Committee on Higher Medical Training on 6th October 2016. The Accreditation Team's remit was to assess the Programme of Specialist Training in Pharmaceutical Medicine against the '*Medical Council Accreditation Standards for Postgraduate Medical Education and Training*' (approved 1st June 2010) and to subsequently formulate a recommendation to the Medical Council's Education, Training and Professional Development Committee.

2. The Team

The Medical Council Accreditation Team is listed in Appendix 1 of this Report. The Council is particularly appreciative of the contribution of external assessors from the UK, Dr Carlo Berti and Prof. Peter Stonier, as well as the national assessors Ms Mairead Boohan, Dr Dermot Power, Dr Consilia Walsh and Mr Declan Ashe, who generously gave of their time and expertise to help with the accreditation process.

The Medical Council also thanks the representatives from the Irish Committee on Higher Medical Training for their co-operation.

3. Documentation

As part of the accreditation process, the ICHMT was asked to complete and document a self-evaluation process based upon the '*Medical Council Accreditation Standards for Postgraduate Medical Education and Training*' (approved 1st June 2010). This documentation was reviewed by the Team.

4. Schedule

The accreditation session included a private morning meeting of the Medical Council Accreditation Team and an in-depth discussion between the Team and representatives from the ICHMT.

5. Appendices

The agenda for the Accreditation Session is attached as Appendix 1. The accreditation standards which were applied throughout this process are attached as Appendix 2.

6. The Report

The '*Medical Council Accreditation Standards for Postgraduate Medical Education and Training*' formed the basis of the evaluation of both the ICHMT and the Programme of Specialist Training in Pharmacology; the observations, comments and recommendations contained in this Report are grouped under the relevant section of these standards.

B. Summary and General Assessment

1. Conclusion and Main Recommendations to the Education, Training and Professional Development Committee.

The Team's main recommendations to the Medical Council's Education, Training and Professional Development Committee are that:

- 1. The Programme of Specialist Training in Pharmaceutical Medicine** should be approved by the Council *with one condition* under the terms of Section 89(3)(a)(i) of the Medical Practitioners Act 2007. This recommendation is made on the grounds of the Medical Council Team's finding that the programme adheres to the rules, criteria, guidelines and standards approved by Council, as specified in Sections 87(3), 88(1)(a), 88(4)(b), 88(4)(d) and 89(3) of the Medical Practitioners Act 2007.

Condition:

- (a) The condition attached to the approval of the programme is that the first full training cycle must be completed leading to the award of a Certificate of Completion of Specialist Training to each successful graduate of the programme.

This approval should be for an initial period of five years from the date of approval by Council.

- 2. The Irish Committee on Higher Medical Training** should be approved by the Council *with one condition* under Section 89(3)(a)(ii) of the Medical Practitioners Act 2007 as the body which may deliver the Programme of Specialist Training in Pharmaceutical Medicine approved under '1' above. This recommendation is made on the grounds of the ICHMT's ongoing compliance with the rules, criteria, guidelines and standards approved by Council as specified in Sections 87(3), 88(1)(a), 88(4)(b), 88(4)(d) and 89(3) of the Medical Practitioners Act 2007, with the caveat of the condition as set out below.

Condition:

- (a) The condition attached to the approval of the body is that the first full training cycle must be completed leading to the award of a Certificate of Completion of Specialist Training to each successful graduate of the programme.

This approval *with conditions* should be for an initial period of five years from the date of approval by Council in accordance with S.I. 529 of 2010.

2. Priority Recommendations to the Body

The Team makes priority recommendations to the ICHMT as follows:

- (a) The ICHMT should flesh out more thoroughly what it has set out under "Assessment and Learning" as the information contained here is not enough to satisfy the requirements on an ongoing basis.
- (b) The curriculum, as a competency based curriculum, should place more emphasis on describing the projects and work that will be undertaken that will lead to the required knowledge, skills and attitudes.

(c) Other Recommendations to the Body:

- (a) The ICHMT should make more explicit how it manages reflective learning and personal appraisal. It is clear from the accreditation that this is being managed effectively and could be clearer in the formal documentation.

(d) Commendations:

The Team would like to commend the ICHMT for the following:

- (a) For the quality of their submission
- (b) For their professionalism and depth of information provided during the accreditation session
- (c) For the skilled design of a novel training programme

(e) Recommended Further Action:

The team noted that there appears to be a resistance to 360 degree feedback. The team also noted that the generic competencies are very much to do with clinical medicine and are not generic competencies in interpersonal, management and leadership areas, i.e. the soft skills that develop the professional. There is also an absence of teaching observation tools. The ICHMT should consider ways to develop the programme in this direction and to incorporate the above.

C. Explanation of Specialty and Service Need

Recognition of Specialty

The specialty of Pharmaceutical Medicine has been recognised by the Medical Council since 19th May 2005, when it was approved by the then Minister of Health and Tanaiste, Mary Harney under Section 38(1) of the Medical Practitioners Act 1978. To date the specialty has not been supported by a programme.

Existing Specialists

There are presently 11 medical practitioners registered as specialists in Pharmaceutical Medicine, who were registered on the basis of assessment of existing training and experience under the relevant provisions of the Medical Practitioners Acts 1978 and 2007.

Purpose of Programme

The proposed programme will be delivered by the Irish Committee on Higher Medical Training, which is a recognised and accredited Postgraduate Training Body that is based in the Royal College of Physicians of Ireland. A standardised framework is applied to all postgraduate training programmes within the ICHMT's remit and the Pharmaceutical Medicine programme follows this model.

Description of Programme

The following extract from the programme sets the context:

Pharmaceutical Medicine is the medical specialty which encompasses the discovery, development, evaluation and licensing of medicines together with their appropriate marketing and ongoing monitoring of their safety in clinical practice (lifecycle management of medicines). The specialty has been evolving over the past 50 years and was recognised as a medical specialty in the UK in 1989 and in Switzerland and Ireland (since 2005); other EU countries are currently in the process of approving the specialty. More recently the EU 7th Framework Programme (which supports scientific research and development activities within Europe) has recognised the importance of appropriate training in the area of pharmaceutical medicine by including several training programmes in its Joint Technology Initiative on Innovative Medicines (IMI JTI).

Although pharmaceutical medicine shares some common themes with clinical pharmacology, it has unique features including the clinical research aspects of drug development, the licensing procedures of medicines and the monitoring of their safety profile in clinical practice (so-called pharmacovigilance). It also includes the provision of accurate and timely medical and technical information to assist healthcare professionals and patients in the appropriate use of medicines and the implementation of regulatory compliance (i.e. adherence to the legal and ethical aspects of medicine usage and promotion) throughout the lifecycle of a medicine. Medical practitioners who work as pharmaceutical physicians undertake these activities in many different areas within the healthcare system and allied services including clinical trial units, academic departments, contract research organisations, national agencies, such as the Health Products Regulatory Authority (formally the Irish Medicines Board), NSAI or National Medicines Information Centre in Ireland as well as the pharmaceutical industry. Although the majority of pharmaceutical physicians (with the possible exception of those undertaking clinical trials) have no direct contact with patients, they are required to be fully registered with the Medical Council of Ireland in order to fulfil their duties.

Pharmaceutical physicians are involved in activities on a daily basis (e.g. evaluating ongoing safety with medicines in practice and promoting evidence-based prescribing) to reduce medication errors, maximise patient benefit and minimise harm with use of medicines. Pharmaceutical physicians interact with other healthcare professionals on a regular basis - on medical information enquiries, in clinical trial activities, in preparing educational materials, including journal articles, textbooks, reference books, formularies, pharmacoeconomic assessments and e-learning materials – all of which encourage rational use of medicines in the interest of patient safety. Pharmaceutical physicians from either the pharmaceutical industry or national agencies may also be called upon by the media to give guidance on drug-related events of public interest.

This training programme will provide the knowledge and competence for a doctor to be trained in all aspects of drug development, the regulation and safe use of medicines, and with good communication skills who will be able to assist healthcare professionals, as well as Pharmacoeconomic and regulatory competent authorities in the rational use of medicines, in the interest of public health.

The Team discussed the status of the specialty in other jurisdictions:

Table 1: Status of Specialty in Other Jurisdictions

Country	Status
United Kingdom	Recognised specialty with programme approved by General Medical Council
Switzerland	Recognised Specialty
Belgium	At advanced stage but not yet approved by Department of Health
USA	Not recognised despite several attempts over last 25 years
Canada	Not recognised

The Team discussed the relationship between the specialty and between Clinical Pharmacology & Therapeutics. The team noted that the United Kingdom's National Health Service incorporates Clinical Pharmacology within its structures, but Pharmaceutical Medicine is not incorporated. The focus of Pharmaceutical Medicine is not on patient care but the development of and registration and safety of medicines.

At the conclusion of the evaluation of the programme against the Council standards, the Team discussed the Curriculum of Training.

- The curriculum of training divides into generic competencies (38 pages) core modules for Pharmaceutical Medicine (16 pages) and specialty modules (8 pages) of which a trainee must pick one module.
- The Team noted that the generic competencies which sit across all ICHMT programmes are accompanied by a caveat which states *"this chapter covers the generic components which are relevant to HST trainees of all specialties but with varying degrees of relevance and appropriateness, depending on the specialty. As such this chapter needs to be viewed as an appropriate guide of the level of knowledge and skills required from all HST Trainees with different application levels in practice."*

D. Evaluation of the Programme

The evaluation of the Programme is based on the Medical Council Accreditation Standards for Postgraduate Medical Education and Training (Appendix 3)

1) CONTEXT OF EDUCATION AND TRAINING

Standard (1) incorporates the following elements:

- 1.1 GOVERNANCE
- 1.2 PROGRAMME MANAGEMENT
- 1.3 EDUCATIONAL EXPERTISE AND EXCHANGE
- 1.4 INTERACTION WITH THE HEALTH SECTOR
- 1.5 CONTINUOUS RENEWAL

Team Evaluation

- The Team were satisfied with the general governance of the programme as it sits within the RCPI's standard structures which have been approved in previous accreditations.

- The Team asked the ICHMT to outline its preparedness for taking on students.
- The Team queried whether the Specialist Training Committee, which has immediate supervisory responsibility for the programme, has been meeting.
- The Team queried how the ICHMT keeps standards similar across all the training sites in such a varied industry, how the overall governance of the scheme will be managed and the oversights and co-ordination processes in place.
- The Team queried the relationship between the programme and the ICHMT.
- The Team expressed concern that public money is being used to entirely fund training that is undertaken in private bodies.

Response of ICHMT

- The ICHMT advised that it has identified three training sites, which are presently under evaluation. The ICHMT advised that an unusual feature of the programme is that trainees won't rotate. This is due to the fact that trainees will be under full-time employment contracts with Pharmaceutical companies, which will not provide scope for the rotations usually undertaken by postgraduate specialist trainees. To compensate, trainees will be provided with more than one trainer. The ICHMT advised that it has ten specialists on the Register at this point in time, all of whom are associated with the ICHMT's Association of Pharmaceutical Physicians. Seven of these are currently undergoing training to be formally recognised as trainers under the RCPI programme. The ICHMT advised that one training site will be the Health Products Regulatory Authority and two large private companies have also made training site applications which are under review.
- The ICHMT confirmed that the Specialist Training Committee (STC) has been meeting. There are presently seven people on the STC which plans to meet 2-3 times per year.
- The ICHMT confirmed that it has put in place the standard programme arrangements for the programme. This includes an e-portfolio, regular reviews, and an external reviewer. The STC will be obliged to ensure that all the trainees either get the competency experience on-site or they will have to attend specialist workshops, practical workshops, which would be run by the other training sites. In the private training sites, the CEO of the organisation will be required to sign up to the programme in order to ensure that the programme is sponsored properly at a senior level.
- The National Specialty Director will work with the trainer to make sure that each aspect of the training programme is adhered to. If the competency isn't available on site the trainee will have to attend a formally recognised practical workshop, the so called 'study days' to develop the competence.
- The ICHMT confirmed that the National Specialty Director sits at ICHMT board level. Common issues such as quality assurance of training and hospital site accreditation are dealt with at training body level to ensure that common standards are applied. Posts are also rated by trainees and the ratings are only published every three years, to preserve the anonymity of trainees. There are training site inspections. Trainees are included on inspections. There is a confidential arrangement with a third party in Cork that trainees can confide in, if they wish to confide outside existing structures.

- The ICHMT confirmed that some of the experience of Occupational Medicine indirectly applies, where sites are concerned, as the RCPI's Faculty of Occupational Medicine already handles sites as diverse as oil rigs and gas companies. The ICHMT observed that due to the nature of the role, Pharmaceutical Medicine sites and posts are already heavily regulated, often having far more SOPs than hospital sites would have.
- The ICHMT confirmed that over half the trainees will be from public bodies such as the Health Products Regulatory Agency and the National Standards Authority of Ireland. The ICHMT advised that public funding is used to pay people in the private sector all the time. The ICHMT advises that it gets a capitation grant of about €2000 per trainee but subsidises everything else. The trainees bring great experience in terms of the commercial aspects and other elements within the programme. In terms of trainers moving from one pharmaceutical firm to another, the signed agreements ensure that the commercial integrity of different sites is respected.

2) THE OUTCOMES OF THE TRAINING PROGRAMME

Standard (2) incorporates the following elements:

- 2.1 PURPOSE OF THE TRAINING ORGANISATION
- 2.2 GRADUATE OUTCOMES

Team Evaluation

- The Team asked the ICHMT to outline its tracking and monitoring procedures for trainees.

Response of ICHMT

- The ICHMT confirmed that the National Specialty Director will report back on post training outcomes and employment patterns, publications and other achievements.

3) THE EDUCATION AND TRAINING PROGRAMME - CURRICULUM CONTENT

Standard (3) incorporates the following elements:

- 3.1 CURRICULUM FRAMEWORK
- 3.2 CURRICULUM STRUCTURE, COMPOSITION AND DURATION
- 3.3 RESEARCH IN THE TRAINING PROGRAMME
- 3.4 FLEXIBLE TRAINING
- 3.5 THE CONTINUUM OF LEARNING

Team Evaluation

- The Team queried how the ICHMT foresees the generic competencies transferring from other specialties to Pharmaceutical Medicine.
- The Team queried whether a situation could arise where an applicant who already has demonstrated skills and competencies in a specific generic context could be required to repeat or demonstrate the competencies again.

- The Team queried how the ICHMT plans to deliver the competencies across the full curriculum when different companies may only have availability for certain types of competency.

Response of ICHMT

- The ICHMT advised that only relevant components of the generic curriculum will need to be covered and it is very much part of training with the trainer and the trainee that they cover those that are relevant and do not have to cover those that are not relevant.
- The ICHMT advised that similar situations arise in Pathology and courses have been successfully customised. The ICHMT only looks at retroactive acceptance of a training programme on a case by case basis. Applicants should contact the ICHMT in advance.
- The ICHMT advised that trainers will have to benchmark themselves against the curriculum and the attainment of specialist registration will reflect this. The e-portfolio will help ensure that all competency areas are covered by each trainee. The fact that trainers will rotate will help optimise competency building. Trainees will have to attain required outcomes as determined by their e-portfolio. Trainees will also have to complete a postgraduate course in Pharmaceutical Medicine. Trainees will also be able to use study days to make up gaps in competencies.

4) THE TRAINING PROGRAMME - TEACHING AND LEARNING

- The Team were satisfied with this element of the submission.

5) THE CURRICULUM - ASSESSMENT OF LEARNING

Standard (5) incorporates the following elements:

- 5.1 ASSESSMENT APPROACH
- 5.2 FEEDBACK AND PERFORMANCE
- 5.3 ASSESSMENT QUALITY
- 5.4 ASSESSMENT OF SPECIALISTS TRAINED OVERSEAS

Team Evaluation

- The Team asked the ICHMT to outline how it plans to accommodate trainees transferring, for example from one Pfizer site to another, to continue their training and how it plans to handle medical practitioners coming from overseas.
- The Team queried how a trainee will know how certain competencies will be delivered, what kind of learning and teaching opportunities they can expect. How will trainees know what kinds of assessments will be undertaken.
- The Team queried whether the ICHMT had considered using 360 degree feedback or multisource feedback tools.
- The Team queried whether the ICHMT plans to carry out an assessment if a trainee resigns from a job.

Response of ICHMT

- The ICHMT confirmed that the programme does facilitate a certain amount of training abroad. The 'out of programme' experience can be undertaken for one, or under circumstances, two years. They can do it but it is still under the remit of the ICHMT. The ICHMT advised that other sites could be accommodated as long as they were prospectively approved by the ICHMT.
- The ICHMT advised that this would have to be agreed with the trainer at the outset of the programme. Trainees will also have to complete forms demonstrating that they have completed certain types of tasks. This will be assessed as part of the end of year assessment. The ICHMT agreed to add extra columns to record suggested teaching methods, and suggested assessment methods, in order to ensure that the trainer and trainee are clear about what is expected in terms of how these are going to be delivered.
- The ICHMT advised that formal 360 tools are difficult and require the use of technology. The type of feedback given constantly focusses on the issue of professionalism, attitude, communication skills and interpersonal skills. However, 360° can be used by a third party under circumstances where a trainee may be struggling around specific issues. The ICHMT noted that the Council has been running a pilot programme on the use of 360 degree feedback as part of performance appraisal and the pilot programme has run smoothly.
- The ICHMT advised that in relation to trainees resigning from jobs, the HSE conducts an assessment. The reasons for leaving are explored with the trainee, to ensure that it is not due to issues with the training programme. The data is returned by each training body back to the HSE.

6) THE CURRICULUM - MONITORING AND EVALUATION

Standard (6) incorporates the following elements:

6.1 ONGOING MONITORING

6.2 OUTCOME EVALUATION

- The Team were satisfied with this element of the submission.

7) IMPLEMENTING THE CURRICULUM – TRAINEES

Standard (7) incorporates the following elements:

7.1 ADMISSION POLICY AND SELECTION

7.2 TRAINEE PARTICIPATION IN TRAINING ORGANISATION GOVERNANCE

7.3 COMMUNICATION WITH TRAINEES

7.4 RESOLUTION OF TRAINING PROBLEMS AND DISPUTES

Team Evaluation

- The Team queried whether the entry requirements are too restrictive, which appear to mainly rely on holding the MRCPI.

- The Team queried what support is available for trainees in industry, where the pressures are different from working in a hospital environment.
- The Team queried what type of employment contract the trainees are on.

Response of ICHMT

- The ICHMT advised that most applicants have the MRCPI or a qualification that the ICHMT deems equivalent, for example the Membership of the Royal College of Surgeons in Ireland (MRCSI) or an equivalent General Practice qualification. Pharmaceutical Medicine medical practitioners are drawn from several branches of medicine.
- The ICHMT advised that study days will play an important role. There will also be regular meetings of the Association of Pharmaceutical Physicians. The trainees will meet with the NSD twice a year. Over time, the number of trained specialists will increase. There are also mandatory courses as well as the RCPI's Online Physician Network, which provides an online forum where trainees can engage with each other. The training co-ordinator will also offer support and can offer that support on a one to one basis if required.
- The ICHMT advised that trainees are on a HSE contract with the site. The contracts are independent of the training programme. The trainees are also under employment contracts. Potential differences contracts between different sites are handled by the requirement that the trainee must already be in a substantive post, so trainees do not feel unfairly disadvantaged by virtue of the type of contract they are on, which might be the case of contracts were allocated in a centralised manner.

8) IMPLEMENTING THE TRAINING PROGRAMME – DELIVERY OF EDUCATIONAL RESOURCES

Standard (8) incorporates the following elements:

8.1 SUPERVISORS, ASSESSORS, TRAINERS AND MENTORS

8.2 CLINICAL AND OTHER EDUCATIONAL RESOURCES

Team Evaluation

- The Team queried whether it is possible, given the nature of the contracts, that line managers could end up being trainers.

Response of ICHMT

- The ICHMT advised that it was seeking to avoid that type of scenario and is looking at a cohort of a number of trainers on site to avoid that occurring. In the past ten years the ICHMT has come up against those issues and has refined its inspection process as well as its confidential feedback line.

9) CONTINUING PROFESSIONAL DEVELOPMENT

Standard (9) incorporates the following elements:

9.1 CONTINUING PROFESSIONAL DEVELOPMENT PROGRAMMES

9.2 RETRAINING

9.3 REMEDIATION

Team Evaluation

- Under discussion of this element of Council's accreditation standards, the Team noted that the ICHMT has already entered into arrangements with the Medical Council under Part 11 of the Medical Practitioners Act 2007 in relation to the establishment of Professional Competence Schemes (PC Schemes).

APPENDIX ONE – TEAMS

ACCREDITATION TEAM	
Prof. Alan Johnson (Chair)	Member of Medical Council and Chair of Education, Training and Professionalism Committee
Prof Peter Stonier	National Programme Director for Pharmaceutical Medicine, Royal College of Physicians, UK
Dr Carlo Berti	Pharmaceutical Physician
Ms Mairead Boohan	Associate Director at the Centre for Medical Education at Queen's University Belfast
Dr Dermot Power	Head of the Intern Training Network for UCD
Mr Declan Ashe	Member of the Education, Training and Professionalism Committee
Ms Consilia Walsh	Member of the Education, Training and Professionalism Committee
COUNCIL EXECUTIVE	
Una O'Rourke	Head of Education, Training and Professionalism
Paul Lyons	Accreditation Manager, Education, Training and Professionalism
Elizabeth Molloy	Accreditation Executive (Postgraduate)
Eoin Keehan	Registration Manager, Registration Section
ICHMT TEAM	
Dr Mary Teeling	National Specialty Director in Pharmaceutical Medicine
Prof. Des Carney	Chairman, Irish Committee on Higher Medical Training
Keith Farrington	Educational Specialist in the RCPI
Patrick Salmon	Pharmaceutical Physician, with the Health Products Regulatory Authority
Hadas Levy	Education and Development Manager, RCPI
ICHMT EXECUTIVE	
Martin McCormack	Head of Operations
Jennifer Shiels	Accreditation Co-ordinator, RCPI
Louise Ó Gógáin	Manager for Medical Training, RCPI

AGENDA	
8.30-8.45am	Introductions and initial accreditation team discussion
8.45am-11.45am	Review of accreditation documentation
11.45am – 12.15pm	Lunch
12.15-14.00	Meeting with College representatives
1.00-1.30 pm	Lunch
14.00-14.15	Private session of accreditation team

Appendix 2 - Medical Council Accreditation Standards for Postgraduate Medical Education and Training

MEDICAL COUNCIL ACCREDITATION STANDARDS FOR POSTGRADUATE MEDICAL EDUCATION AND TRAINING

1. CONTEXT OF EDUCATION AND TRAINING

1.1 GOVERNANCE

- 1.1.1 The training organisation's governance structures and its education and training, assessment and continuing professional development functions are defined.
- 1.1.2 The governance structures describe the composition and terms of reference for each committee, and allow all relevant groups to be represented in decision-making.
- 1.1.3 The training organisation's internal structures give priority to its educational role relative to other activities.

1.2 PROGRAMME MANAGEMENT

- 1.2.1 The training organisation has established a committee or committees with the responsibility, authority and capacity to direct the following key functions:
 - planning, implementing and reviewing the training programme(s) and setting relevant policy and procedures
 - setting and implementing policy and procedures relating to the assessment of overseas-trained specialists
 - setting and implementing policy on continuing professional development and reviewing the effectiveness of continuing professional development activities.
- 1.2.2 The training organisation's education and training activities are supported by appropriate resources including sufficient administrative and technical staff.
- 1.2.3 Funding and Resource Allocation - there must be a clear line of responsibility and authority for budgeting of training resources. The training bodies must be adequately funded in order to plan and deliver the programme.

1.3 EDUCATIONAL EXPERTISE AND EXCHANGE

- 1.3.1 The training organisation uses educational expertise in the development, management and Continuous improvement of its education, training, assessment and continuing professional development activities, as required.
- 1.3.2 The training organisation collaborates with other educational institutions and compares its curriculum, training programme and assessment with that of other relevant programmes.

1.4 INTERACTION WITH THE HEALTH SECTOR

- 1.4.1 The training organisation seeks to maintain constructive working relationships with relevant health departments and government, non-government and community agencies to promote the education, training and ongoing professional development of medical specialists.
- 1.4.2 The training organisation works with healthcare institutions to facilitate clinicians employed by them to contribute to high quality teaching and supervision, and to foster peer review and professional development.

1.5 CONTINUOUS RENEWAL

- 1.5.1 The training organisation reviews and updates structures, functions and policies relating to education, training and continuing professional development to rectify deficiencies and to meet changing needs.

2. THE OUTCOMES OF THE TRAINING PROGRAMME

2.1 PURPOSE OF THE TRAINING ORGANISATION

- 2.1.1 The purpose of the training organisation includes setting and promoting high standards of medical practice, training, research, continuing professional development, and social and community responsibilities.
- 2.1.2 In defining its purpose, the training organisation has consulted fellows and trainees, and relevant groups of interest.

2.2 GRADUATE OUTCOMES

- 2.2.1 The training organisation has defined graduate outcomes for each training programme including any sub-specialty programmes. These outcomes are based on the nature of the discipline and the practitioners' role in the delivery of health care. The outcomes are related to community need.
- 2.2.2 The outcomes address the broad roles of practitioners in the discipline as well as technical and clinical expertise.
- 2.2.3 Outcomes must reflect domains of professionalism as defined by the Medical Council with particular reference to patient safety
- 2.2.4 The training organisation makes information on graduate outcomes publicly available.

3. THE EDUCATION AND TRAINING PROGRAMME - CURRICULUM CONTENT

3.1 CURRICULUM FRAMEWORK

- 3.1.1 For each of its education and training programmes, the training organisation has a framework for the curriculum organised according to the overall graduate outcomes. The framework is publicly available.

3.2 CURRICULUM STRUCTURE, COMPOSITION AND DURATION

- 3.2.1 For each component or stage, the curriculum specifies the educational objectives and outcomes, details the nature and range of clinical experience required to meet these objectives, and outlines the syllabus of knowledge, skills and professional qualities to be acquired.
- 3.2.2 Successful completion of the training programme must be certified by a diploma or other formal award.

3.3 RESEARCH IN THE TRAINING PROGRAMME

- 3.3.1 The training programme includes formal learning about research methodology, critical appraisal of literature, scientific data and evidence-based practice, and encourages the trainee to participate in research.
- 3.3.2 The training programme allows appropriate candidates to enter research training during specialist education and to receive appropriate credit towards completion of specialist training.

3.4 FLEXIBLE TRAINING

- 3.4.1 The programme structure and training requirements recognise part-time, interrupted and other flexible forms of training.
- 3.4.2 There are opportunities for trainees to pursue studies of choice, consistent with training programme outcomes, which are underpinned by policies on the recognition of prior learning. These policies recognise demonstrated competencies achieved in other relevant training programmes both here and overseas, and give trainees appropriate credit towards the requirements of the training programme.

3.5 THE CONTINUUM OF LEARNING

- 3.5.1 The training organisation contributes to articulation between the specialist training programme and prevocational and undergraduate stages of the medical training continuum.

4. THE TRAINING PROGRAMME - TEACHING AND LEARNING

- 4.1.1 The training is practice-based involving the trainees' personal participation in relevant aspects of the health services and, for clinical specialties, direct patient care.
- 4.1.2 The training programme includes appropriately integrated practical and theoretical instruction.
- 4.1.3 The training process ensures an increasing degree of independent responsibility as skills, knowledge and experience grow.

5. THE CURRICULUM - ASSESSMENT OF LEARNING

5.1 ASSESSMENT APPROACH

- 5.1.1 The assessment programme, which includes both summative and formative assessments, reflects comprehensively the educational objectives of the training programme.
- 5.1.2 The training organisation uses a range of assessment formats that are appropriately aligned to the components of the training programme.
- 5.1.3 The training organisation has policies relating to disadvantage and special consideration in assessment, including making reasonable adjustments for trainees with a disability.

5.2 FEEDBACK AND PERFORMANCE

- 5.2.1 The training organisation has processes for early identification of trainees who are under performing and for determining programmes of remedial work for them.
- 5.2.2 The training organisation facilitates regular feedback to trainees on performance to guide learning.
- 5.2.3 The training organisation provides feedback to supervisors of training on trainee performance, where appropriate.

5.3 ASSESSMENT QUALITY

- 5.3.1 The training organisation has a policy on the evaluation of the reliability and validity of assessment methods, the educational impact of the assessment on trainee learning, and the feasibility of the assessment items. It introduces new assessment methods where required.

5.4 ASSESSMENT OF SPECIALISTS TRAINED OVERSEAS

- 5.4.1 The processes for assessing of specialists trained overseas are in accordance with the principles outlined by the Irish Medical Council

6. THE CURRICULUM - MONITORING AND EVALUATION

6.1 ONGOING MONITORING

- 6.1.1 The training organisation regularly evaluates and reviews its training programmes. Its processes address curriculum content, quality of teaching and supervision, assessment and trainee progress.
- 6.1.2 Supervisors and trainers contribute to monitoring and to programme development. Their feedback is systematically sought, analysed and used as part of the monitoring process.
- 6.1.3 Trainees contribute to monitoring and to programme development. Their confidential feedback on the quality of supervision, training and clinical experience is systematically sought, analysed and used in the monitoring process. Trainee feedback is specifically sought on proposed changes to the training programme to ensure that existing trainees are not unfairly disadvantaged by such changes.

6.2 OUTCOME EVALUATION

- 6.2.1 The training organisation maintains records on the graduates of its training programme, is developing methods to measure outcomes of training and is collecting qualitative information on outcomes.
- 6.2.2 Supervisors, trainees, health care administrators, other health care professionals and consumers contribute to evaluation processes.

7. IMPLEMENTING THE CURRICULUM – TRAINEES

7.1 ADMISSION POLICY AND SELECTION

- 7.1.1 A clear statement of principles underpins the selection process, including the principle of merit-based

selection.

7.1.2 The processes for selection into the training programme

- are based on the published criteria and the principles of the training organisation concerned
- are evaluated with respect to validity, reliability and feasibility
- are transparent, rigorous and fair
- are capable of standing up to external scrutiny
- include a formal process for review of decisions in relation to selection, and information on this process is outlined to candidates prior to the selection process.

7.1.3 The training organisation documents and publishes its selection criteria. Its recommended weighting for various elements of the selection process, including previous experience in the discipline, is described. The marking system for the elements of the process is also described.

7.1.4 The training organisation publishes its requirements for mandatory experience, such as rotation through a range of training sites. The criteria and process for seeking exemption from such requirements are made clear.

7.1.5 The training organisation monitors the consistent application of selection policies across training sites and/or regions.

7.2 TRAINEE PARTICIPATION IN TRAINING ORGANISATION GOVERNANCE

7.2.1 The training organisation has formal processes and structures that facilitate and support the involvement of trainees in the governance of their training.

7.3 COMMUNICATION WITH TRAINEES

7.3.1 The training organisation has mechanisms to inform trainees about the activities of its decision-making committees, in addition to communication by the trainee organisation or trainee representatives.

7.3.2 The training organisation provides clear and easily accessible information about the training programme, costs and requirements, and any proposed changes.

7.3.3 The training organisation provides timely and correct information to trainees about their training status to facilitate their progress through training requirements.

7.4 RESOLUTION OF TRAINING PROBLEMS AND DISPUTES

7.4.1 The training organisation has processes to address confidentially problems with training supervision and requirements.

7.4.2 The training organisation has clear impartial pathways for timely resolution of training-related disputes between trainees and supervisors or trainees and the organisation.

7.4.3 The training organisation has reconsideration, review and appeals processes that allow trainees to seek impartial review of training-related decisions, and makes its appeals policies publicly available.

7.4.4 The training organisation has a process for evaluating de-identified appeals and complaints to determine if there is a systems problem.

8. IMPLEMENTING THE TRAINING PROGRAMME – DELIVERY OF EDUCATIONAL RESOURCES

8.1 SUPERVISORS, ASSESSORS, TRAINERS AND MENTORS

- 8.1.1 The training organisation has defined the responsibilities of hospital and community practitioners who contribute to the delivery of the training programme and the responsibilities of the training organisation to these practitioners.
- 8.1.2 The training organisation has processes for selecting supervisors who have demonstrated appropriate capability for this role. It facilitates the training of supervisors and trainers.
- 8.1.3 The training organisation routinely evaluates supervisor and trainer effectiveness including feedback from trainees and offers guidance in their professional development in these roles.
- 8.1.4 The training organisation has processes for selecting assessors in written, oral and performance-based assessments who have demonstrated relevant capabilities.
- 8.1.5 The training organisation has processes to evaluate the effectiveness of its assessors/examiners including feedback from trainees, and to assist them in their professional development in this role.
- 8.1.6 Organisation and development of trainers – instructional activities must be included as responsibilities in the work schedules of trainers and their relationship to work schedules of trainees must be described.

8.2 CLINICAL AND OTHER EDUCATIONAL RESOURCES

- 8.2.1 The training organisation has a process and criteria to select and recognise hospitals, sites and posts for training purposes. The accreditation standards of the training organisation are publicly available.
- 8.2.2 The training organisation specifies the clinical and/or other practical experience, infrastructure and educational support required of an accredited hospital/training position in terms of the outcomes for the training programme. It implements clear processes to assess the quality and appropriateness of the experience and support offered to determine if these requirements are met.
- 8.2.3 The training organisation's accreditation requirements cover: orientation, clinical and/or other experience, appropriate supervision, structured educational programmes, educational and infrastructure supports such as access to the internet, library, journals and other learning facilities, continuing medical education sessions accessible to the trainee, dedicated time for teaching and training and opportunities for informal teaching and training in the work environment.
- 8.2.4 The training organisation works with the health services to ensure that the capacity of the health care system is effectively used for service-based training, and that trainees can experience the breadth of the discipline. It uses an appropriate variety of clinical settings, patients and clinical problems for training purposes, while respecting service functions.
- 8.2.5 The training organisation should monitor the working environment to ensure it is a safe environment for training.

9. CONTINUING PROFESSIONAL DEVELOPMENT

9.1 CONTINUING PROFESSIONAL DEVELOPMENT PROGRAMMES

- 9.1.1 The training organisation's professional development programmes are based on self-directed learning. The programmes assist participants to maintain and develop knowledge, skills and attitudes essential for meeting the changing needs of patients and the health care delivery system, and for responding to scientific developments in medicine as well as changing societal expectations.

- 9.1.2 The training organisation determines the formal structure of the CPD programme in consultation with stakeholders, taking account of the requirements of relevant authorities such as medical boards.
- 9.1.3 The process and criteria for assessing and recognising CPD providers and/or the individual CPD activities are based on educational quality, the use of appropriate educational methods and resources, and take into consideration feedback from participants.
- 9.1.4 The training organisation documents the recognised CPD activities of participants in a systematic and transparent way, and monitors participation.
- 9.1.5 The training organisation has mechanisms to allow doctors who are not its Members and/or Fellows to access relevant continuing professional development and other educational opportunities.
- 9.1.6 The training organisation has processes to counsel fellows who do not participate in ongoing professional development programmes.

9.2 RETRAINING

- 9.2.1 The training organisation has processes to respond to requests from the Medical Council for retraining of doctors who have been absent from practice for a period of time.

9.3 ASSESSMENT AND REMEDIATION

- 9.3.1 The training organisation has processes to respond to requests from the Medical Council for assessment and remediation of doctors where concerns have been identified that these doctors may be under-performing.

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and

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