



EU Directive 2013/55/EU
The recognition of professional
qualifications

Proposing a Common Training Framework
for Specialists in Laboratory Medicine
Across the European Union.



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Executive summary

Laboratory medicine is the speciality that underpins modern medicine's understanding of health and disease. It is estimated that up to 70% of all medical decisions are based on data and information provided by Medical Laboratories whose contributions include screening and early detection of disease, differential diagnosis, monitoring, management/treatment of patients, and their prognostic assessment. There are an estimated 30,000 Specialists in Laboratory Medicine across the 28 countries of the European Union – of whom approximately 40% are from a medical background, 30% are from scientific and 30% from pharmacy backgrounds.

Under EU Directive 2013/55/EU the European Community Confederation of Clinical Chemistry and Laboratory Medicine (EC4) proposes the establishment of a Common Training Framework for harmonisation of education at a high level and to ensure patients' safety is protected during professional migration of specialists across EU borders. The key elements outlined in this submission:-

- Defines 10 years as minimum training with a Master of Science (MSc or equivalent) qualification after an initial 5 years academic period and an EC4-approved exit qualification after a further 4 years vocational training.
- Includes expectations for education and training to follow the EC4 syllabus that also identifies the competencies required to assure patients that they receive safe and high quality care.
- Requires specialists to be included in a professional Register in their home country (if available) and to maintain their competence and knowledge base through participation in Continuous Professional Development activities
- Provides a code of conduct for its practitioners based on the European value (**CEPLIS**)
- Describes the breakdown of specialist training expectations across laboratory medicine

Through its Register Commission established in 1997, EC4 has already recognised over 3000 registrants able to meet the requirements of this framework. This paper is submitted on their behalf and on behalf of the national society representatives who have been instrumental in its compilation



1. Setting the scene

It is estimated that up to 70% of all medical decisions are based on data and information provided by laboratory medicine. It is the speciality that underpins modern medicine's understanding of health and disease. Its disciplines include clinical chemistry/immunology, haematology/blood transfusion, microbiology/virology/parasitology, reproductive medicine, and genetics. Its contributions include screening and early detection of disease, differential diagnosis, monitoring, management and treatment of patients, and their prognostic assessment. This contribution continues to grow through research and development, technological advances, and the increasing knowledge and skills base of its specialist practitioners across the 28 EU Member States

The estimated 30,000 specialists in laboratory medicine include medical (~40%), scientific (~30%) and pharmacy (~30%) trained staff (1). Whilst specialists with a medical Background have long enjoyed automatic recognition of their qualifications during cross-border professional migration as a "sectorial profession" the same is not true for the 60% specialists under the "general system". Despite largely equivalent education and training they have been subject to 'compensation measures' by host Member States

This document supports the goals of the new directive by submitting a Common Training Framework for Specialists in Laboratory Medicine with scientific and pharmacy backgrounds.

Its central tenet is protecting patients' safety during professional migration. The proposed framework builds on the infrastructure developed since 1994 by the European Community Confederation of Clinical Chemistry and Laboratory Medicine (EC4)

2. The contribution of specialists in laboratory medicine to healthcare

2.1 Roles and responsibilities

Whilst the scope of overall practice varies across the Member States the overlap is considerable such that common roles and responsibilities can be drawn out as follows:



- Provision of clinical leadership to direct and determine the scope and organisation of laboratory medicine contribution required for local populations
- Working from an extensive, up to date knowledge and evidence base to ensure best practice
- Ability to work in a clinical environment to initiate tests and interpret results that aid in differential diagnosis, patient management and prognostication, as appropriate
- Supporting research and development: innovating and implementing new technologies; initiating, conducting and evaluating clinical research; ensuring appropriate knowledge management
- Responsibility for safety of patients through participation and/or delivering quality assurance programmes, undertaking continuous audit and evaluation, understanding of ethical, legal and governance considerations
- Participation and/or leading teaching, education and training programmes

2.2 The context of their contributions

Knowledge, skills and competencies arm the specialist to provide solutions to ever changing demands. In part these demands are predicated by individual member state priorities but, increasingly, common themes emerge in the provision of healthcare across the Community. Ongoing changes which require specialists' responses include:

- a) Greater clinical governance expectations for evidence-based protocol driven care in the application of diagnostic tests
- b) A shift from voluntary to mandatory accreditation of activities that expects standards to be met in laboratory management and personnel, premises/environment, technology/ information systems, pre-and post-analytical phases.
- c) A shift in funding priorities to improving public health as a means of reducing later, more costly hospital admissions.
- d) Increasing demands for professionals to be registered and/or professional practice to be regulated to protect public and patients' interests.

2.3 Ensuring patients' safety

Patients expect quality if they turn to a medical laboratory. They expect that for their medical laboratory diagnosis the right samples are taken, at the right time and in the



right way. They expect that the results and their interpretation are state of the art and in the hands of recognised professionals. Untimely reporting, untimely interpretation of laboratory results, or errors in laboratory results can be immediately life threatening. Examples include blood group and antibody determination for blood transfusion, glucose measurements for insulin dosing in diabetes patients, potassium analysis in cardiac patients, pH blood gases for patients on artificial respiration, coagulation determinations for oral anticoagulation medication, or a pregnancy test for a patient in an emergency unit deciding whether an appendix operation can be done or not.

As an example the case of measurement of glucose on a handheld meter by a Dutch diabetes patient is discussed briefly. This patient used an approved glucose meter. At his biannual assessment the patient measured a glucose value of 10 mmol/L on his own meter. The plasma result of the laboratory was 5 mmol/L. The patient was asked to send in his meter. Assessment revealed that the meter showed a structural positive bias of 50%, caused by an unknown factor. The patient was on insulin and frequently had hypoglycaemia because of overdosing insulin. Thus, for evaluation of measurements by patients it is necessary to assess the combination of the patient's handlings on his own meter (which should be an approved meter), the patient's strips and the patient's blood. The expertise of an accredited laboratory is essential for such evaluation

The calibration of methods for the same analysis sometimes is extremely difficult. This hampers the transposition of laboratory data from one laboratory to another. Consequently in the Directive 98/79 EC on in vitro medical devices, traceability is required to reference systems. Specialists in laboratory medicine can ensure that such traceability is in place. Most laboratories are (or are in the process of being) accredited according to ISO/EN 15189 Norm in which particular requirements for medical laboratories are formulated.

To reassure patients that their safety is not at stake when medical laboratory investigation is necessary it must be clear that *a recognised specialist has end responsibility and offers advice and consultation.*

3. Demographics of the profession across the European Union

In countries where the profession is regulated a post-academic training of four to seven years is required to be able to practise. The total number of years regarding the level of



training, including academic education and post-graduate training, varies between nine and thirteen. Regardless of the basic academic background (medicine, pharmacy or science), the profession is practised at fully comparable level with respect to responsibilities, advisory or consulting function and competences in most countries. In some countries medically educated practitioners see patients, in addition to the laboratory and advising responsibilities. In other countries also science and pharmacy educated specialists inform, advice and counsel patients. In some countries (Ireland, The Netherlands) medically educated professionals are a minority, in other countries (Austria, Estonia, Lithuania, Sweden) the profession is exclusively practiced at senior level by medically educated specialists.

An inventory of the existing situation across the Community is a key pre-requisite to defining a Common Training Framework and an inventory for science/pharmacy educated specialists is presented.

3.1 Inventory for scientists/pharmacists

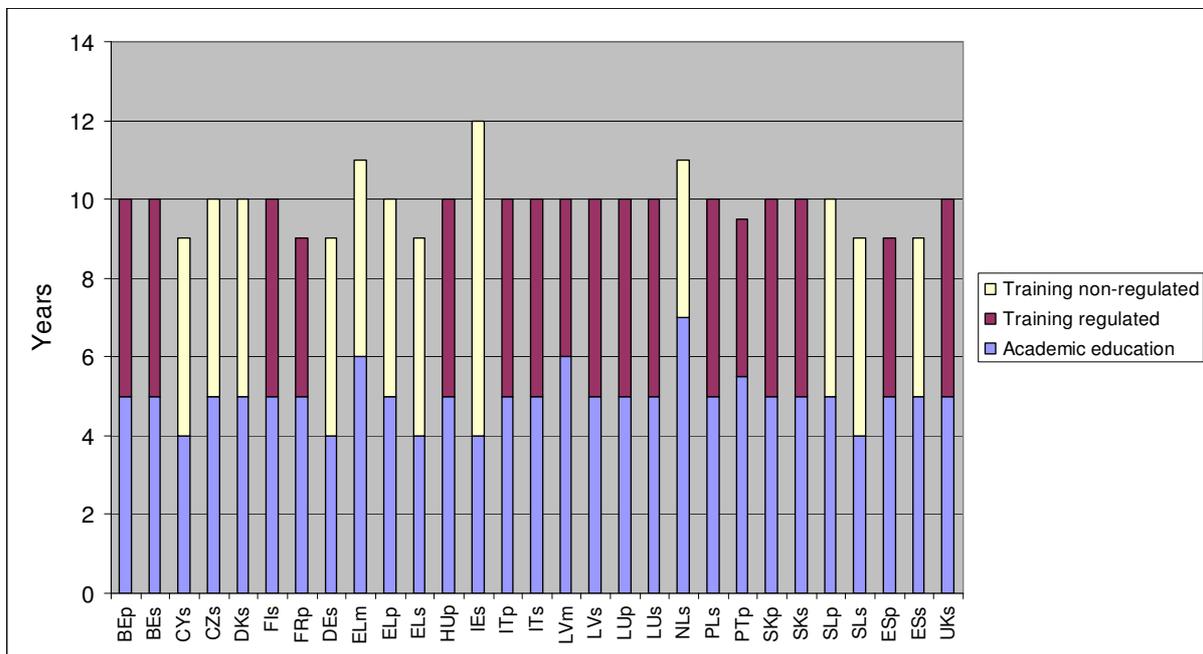
In 20 out of 28 member states the profession is practised by science/pharmacy educated professionals - Austria, Bulgaria, Estonia, Lithuania, Romania, Sweden and Malta allowing only medically educated professionals at senior level.

Figure 1 shows the level of training of specialists not enjoying automatic recognition as provided by the directive. In the regulated member states the required academic education is five years (six for medicine in Latvia) and the post-graduate training ranges from 4-6 years. In the non-regulated member states Cyprus, Germany, Greece, Ireland and Slovenia, four years of academic education in science is accepted to enter the training phase. In these member states post-graduate training required is 5 to 8 years. Ireland is the only member states accepting 4 years bachelor education to enter an 8 year consultant training. In The Netherlands in addition to the five years masters in science two years of academic research are required to enter the training. The highest level of training required in a regulated member states is in Belgium, France, Hungary, Italy, Latvia, Luxembourg, Poland and Slovakia, where five years of academic education and an additional five years of training are required. In the UK, demanding five years academic education, two years of further training are required for registration as a clinical scientist, and an additional three years of training are required before entry to the final examination of FRCPath, which is required to be



appointed as a consultant clinical biochemist, which is the position of specialists in all other countries.

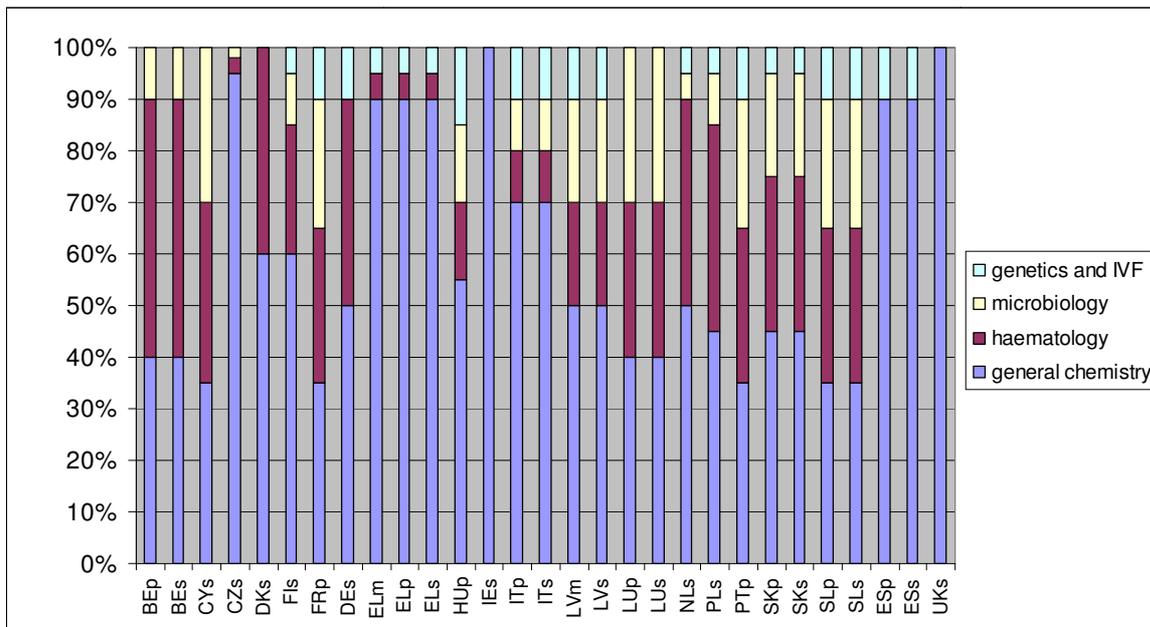
Figure 1 Level of training (specialists not enjoying automatic recognition).



In figure 2 the training content and the area of activities is shown. In all member states the training content reflects the activities which the professional is entitled to pursue. Four different fields are included in the training of most countries. General chemistry includes general biochemistry and pathophysiology, endocrinology, humoral immunology, therapeutic drug monitoring and toxicology. Haematology includes cytometry, coagulation, cellular immunology and transfusion medicine. Microbiology includes bacteriology, mycology, virology and parasitology. Genetics and IVF includes fertility testing, semen investigation, semen preparation and in vitro fertilization. Molecular biology or nucleic acid testing is considered a technique and is included in all fields. In several countries parts of the training are in conformity with the European syllabus for various fields. Nevertheless there are differences between the countries both in number of fields and in depth of training. In most countries the training content and area of activities includes the four fields.



Figure 2 Training content and area of activities (specialists not enjoying automatic recognition).



In Belgium and Luxembourg three fields are covered, whilst in Spain (pharmacy educated) two. In UK multi-disciplinary training is provided under the Modernising Scientific Careers programme before single discipline specialisation is pursued. In the non-regulated countries the four fields are covered in The Netherlands and Slovenia. In Cyprus, Germany, Czech Republic and in Greece three fields are covered, in Denmark and Spain (science educated) two, while in Ireland focus is on one field.

In summary, for the regulated countries the highest requirements in terms of duration and content are, equivalently, in France, Hungary, Italy, Poland, Slovakia and UK. The training content varies from country to country. However, in a large majority of the regulated countries three to four fields are covered.



4. The shape of a Common Training Framework

The proposed framework builds on the infrastructure developed since 1994 by the European Community Confederation of Clinical Chemistry and Laboratory Medicine, a representative organisation of the 28 EU member states that promotes recognition of the profession. Its objectives, governance structure and inter-relationships are described in Appendix 2. The key elements of the framework that can allow an individual to be recognised as a specialist in laboratory medicine by EC4:

- Defines 10 years as minimum training with a Master of Science (MSc or equivalent) qualification after an initial 5 year academic period and an EC4-approved exit qualification after a further 4 years vocational training.
- Includes expectations for education and training to follow the EC4 syllabus that also identifies the competencies required to assure patients that they receive safe and high quality care.
- Requires specialists to be included in a professional register (if available) in their home country and to maintain their competence and knowledge base through participation in Continuous Professional Development activities
- Provides a code of conduct for its practitioners

Based on the requirements of regulated countries the framework should have a training content including:

- general chemistry of at least 35%
- general chemistry plus haematology of at least 65%
- flexibility as to the remaining 35%, including general chemistry, haematology, microbiology, and genetics and IVF in a proportion consistent with the requirements in the country of destination, consisting of work experience, accredited courses, relevant exams of the national training programs, traineeships.

In identifying 4 fields of laboratory medicine, training should include sub-specialisation in each of these fields as follows:

- General chemistry includes general biochemistry, pathophysiology, endocrinology, humoral immunology, therapeutic drug monitoring and toxicology.
- Haematology includes cytometry, coagulation, cellular immunology and transfusion medicine.



- Microbiology includes bacteriology, mycology, virology and parasitology.
- Genetics and IVF includes fertility testing, semen investigation, semen preparation and in vitro fertilization.

Molecular biology or nucleic acid testing is considered a technique and is included in all fields.

Through its Register Commission, more than 3000 national representatives have submitted successful applications to EC4's Foundation Board for recognition as Specialist in Laboratory Medicine. For individual applicants a number of peer reviewed publications describe the standards they are required to meet within EC4's governance structure for high quality, safe specialist practice:

- a) Background to the EC4 Register and EC4 activities(2)
- b) A guide to the Register outlining the application process (3)
- c) The EC4 syllabus for post-graduate education and training in laboratory medicine (4)
- d) A definition of the term Specialist in Laboratory Medicine (5)
- e) Competencies required to practice at consultant level in laboratory medicine (6)
- f) A code of conduct (7)

5. Concluding remarks

- The proposed Common Training Framework for scientific and pharmacy trained specialists in laboratory medicine takes important steps to reducing inequality and uncertainty for patients seeking medical laboratory healthcare across the EU Community.
- Underpinned by the evidence and history of EC4's infrastructure the framework provides a template for ensuring the delivery of equivalent high quality, safe practice across the Community but does not compromise individual member states' needs for local education and training programmes that reflect local needs and priorities.
- In identifying over 3000 Registrants to date ,EC4 potentially provides the evidence for issue of a European professional card that recognises the harmonisation provided by the CTF accepted by 10 Member States



- The CTF supports and potentially contributes to enabling the goals of EU Directive 2013/55/EU for increasing professional mobility, supporting a more equitable distribution of skills and expertise across the Union, and enhancing patient safety

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