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# A proposed Common Training Framework for Specialists in Laboratory Medicine under EU Directive 2013/55/EC (The Recognition of Professional Qualifications)

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**Abstract:** European Union (EU) Directive 2013/55/EC (The Recognition of Professional Qualifications) allows Member States to decide on a common set of minimum knowledge, skills and competences that are needed to pursue a given profession through a Common Training Framework. To be adopted the framework must combine the knowledge, skills and competences of at least one third of the Member

States. Professionals who have gained their qualifications under a Common Training Framework will be able to have these recognised automatically within the Union. The backbone of the European Federation of Clinical Chemistry and Laboratory Medicine's (EFLM) proposed Common Training Framework for non-medical *Specialists in Laboratory Medicine* is outlined here. It is based on an Equivalence of Standards in education, training, qualifications, knowledge, skills, competences and the professional conduct associated with specialist practice. In proposing the recognition of specialist practice EFLM

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has identified 15 EU Member States able to meet Equivalence and in whom the profession and/or its training is regulated (an additional EU Commission requirement). The framework supports and contributes to the Directive's enabling goals for increasing professional mobility, safeguarding consumers and ensuring a more equitable distribution of skills and expertise across the Member States. It represents EFLM's position statement and provides a template for professional societies and/or competent authorities to engage with the EU Commission.

**Keywords:** Common Training Framework; Equivalence of Standards; EU Directive 2013/55/EC; Recognition of Professional Qualifications; Specialist in Laboratory Medicine.

## 1 Setting the scene

It has been estimated that up to 70% of all medical decisions are based on data and information provided by laboratory medicine [1, 2]. 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 for the 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.

The estimated 30,000 specialists in laboratory medicine across the European Union (EU) include medical (~40%), scientific (~30%) and pharmacy (~30%) trained staff [3]. Whilst specialists with a medical background have long enjoyed automatic recognition of their qualifications during cross-border professional migration as one of seven "sectorial professions" identified in EU Directive 2005/36/EU [4] the same is not true for the 60% of scientific and pharmacy-trained specialists under the "general system". However, through its amendment of the 2005 directive, Directive 2013/55/EU (The Recognition of Professional Qualifications) [5] the European Union:

- Provides opportunities for the mutual recognition of qualifications for the estimated 600 professions in the "general system" which in turn,
- Helps catalyse a more rapid and equitable distribution of human resource and services across the Union,
- Supports individuals seeking unhindered professional migration across EU borders,

- Identifies unique professional contributions that in turn can help obviate the need for "compensation measures" in which Member States impose, for example, re-training, new qualifications, aptitude tests, and adaptation periods on each others' professionals which may needlessly delay and deter migration.

Recognising that safeguards need to be in place to ensure the health and safety of consumers (for example, patients in the case of healthcare) is protected when professionals migrate to a host/receiving state the 2013 Professional Qualifications Directive allows Member States to decide on a common set of minimum knowledge, skills and competences that are needed to pursue a given profession through a Common Training Framework. To be adopted the framework must combine the knowledge, skills and competences of at least one third of the Member States. Professionals who have gained their qualifications under a Common Training Framework will be able to have these recognised automatically without further 'compensation measures' being imposed.

Proposing the recognition of specialist practitioners in laboratory medicine is commensurate with the European Federation of Clinical Chemistry and Laboratory Medicine's (EFLM) role and contribution in ensuring equitable, high quality, safe services for patients across the European Union's single market. In 1998, EFLM's forerunner organisation, the European Communities Confederation of Clinical Chemistry and Laboratory Medicine (EC4) established an Equivalence of Standards amongst the EU Member States based on education, training, qualifications, continuous professional development and professional conduct that it considered commensurate with the role of a *European Specialist in Laboratory Medicine* (EuSpLM) [6]. Individuals able to meet the standards are invited to join EFLM's Register of specialists [7]. The Equivalence standards together with the expected knowledge, skills and competencies for practicing at specialist level form the backbone of a proposed Common Training Framework which is outlined here. In setting the scene for the proposed framework an overview is first provided of specialists' unique contributions and their demographic profile in relation to further stipulations laid down by the 2013 Professional Qualifications Directive for example on regulation status and adoption of professional titles. The proposed Common Training Framework represents EFLM's position statement and offers the EU Member States a template for submission to the EU Commission.

## 2 The contribution of specialists in laboratory medicine to better health and best care

### 2.1 Roles and responsibilities

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

- Provision of clinical and scientific leadership to direct and determine the scope and organisation of laboratory medicine services that are appropriate 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 guide diagnostic testing and interpretation of results that aid in the screening of healthy populations, differential diagnosis of disease in patients, their appropriate treatment and management, and assessment of their prognosis.
- Leading and supporting research and development: innovating and implementing new technologies; initiating, conducting and evaluating clinical research; ensuring appropriate knowledge management
- Responsibilities for patient safety 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
- Providing the clinical leadership that focuses on patients' needs and contributes to the evolution of health and healthcare services.

### 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, increasingly the appropriate application of Point of Care Testing in environments beyond the laboratory.

- b) The appropriate application of evolving artificial intelligence-driven digital technology and e-healthcare solutions that catalyse service reconfigurations and allow more effective use of resources.
- c) A shift from voluntary to mandatory accreditation that places new expectations and standards to be met in laboratory management, support for human resource, premises/environment, technology/ information systems, and support for pre-and post-analytical phases.
- d) A shift in funding priorities to improving public health as a means of reducing later, more costly hospital admissions that calls for new ways of working beyond the laboratory.
- e) Expectations for professionals and professional practice to be appropriately registered and/or regulated to protect public and patients' interests and safety.

## 3 The demographics of the profession

Information provided by 26 national societies who are members of EFLM indicate that pharmacists and scientists are the majority specialist practitioners in 15 EU Member States. Medical staff predominate in Austria, Belgium, Bulgaria, Denmark, Germany, Greece, Hungary, Ireland, Latvia, Malta and Sweden. Whilst pharmacists predominate in France, Portugal and Spain, scientists predominate in Croatia, Cyprus, Czech Republic, Estonia, Finland, Italy, Lithuania, Netherlands, Poland, Romania, Slovenia and Slovak Republic. There are reportedly no non-medical specialists practitioners in Malta and Austria. In collating the demographic information no response was received from Luxembourg.

The scope of non-medical practice is outlined in Table 1, the unique role that distinguishes non-medical specialists from their medical colleagues in many Member States is the latter's provision of direct clinical care. It is estimated that over 80% of practitioners working in the Union at specialist level are able to meet the polyvalent scope of practice in clinical chemistry, haematology, and microbiology [3] set by EFLM's Equivalence of Standards.

Table 2 highlights that EFLM's Equivalence of Standards can be met in 19 of the EU's 27 Member States. In 15 (53% of EU Member States) of these the profession or specialist training is regulated at government level, a prerequisite to proposing a Common Training Framework. The table also highlights the professional titles that would benefit from automatic recognition under the Professional Qualifications Directive on adoption of a Common Training Framework. The diversity of professional titles reflects a

**Table 1:** Fields of non-medical specialist practice in laboratory medicine across EU member states.

	Biochemistry	Endocrinology	Immunology	Haematology	Blood transfusion	Microbiology
Austria	N/A	N/A	N/A	N/A	N/A	N/A
Belgium	Yes	Yes	Yes	Yes	Yes	Yes
Bulgaria	Yes	Yes	Yes	Partial	No	No
Croatia	Yes	Yes	Yes	Yes	Partial	No
Cyprus	Yes	Yes	Yes	Yes	Partial	Yes
Czech Republic	Yes	No	Yes	Yes	Yes	Yes
Denmark	Yes	Yes	Yes	Yes	No	No
Estonia	Yes	Yes	Yes	Yes	Yes	Yes
Finland	Yes	Yes	Partial	Yes	Partial	Partial
France	Yes	Yes	Yes	Yes	Yes	Yes
Germany	Yes	Yes	Yes	Yes	No	No
Greece	Yes	Yes	Yes	Yes	Yes	No
Hungary	Yes	Yes	Partial	Yes	No	No
Ireland	Yes	Yes	No	No	No	No
Italy	Yes	Yes	Yes	Yes	No	Yes
Latvia	Yes	Yes	Yes	Yes	Yes	Yes
Lithuania	Yes	Yes	Yes	Yes	Yes	Yes
Luxembourg						
Malta	N/A	N/A	N/A	N/A	N/A	N/A
Netherlands	Yes	Yes	Yes	Yes	Yes	No
Poland	Yes	Yes	Yes	Yes	Partial	No
Portugal	Yes	Yes	Yes	Yes	Partial	Yes
Romania	Yes	Yes	Yes	Yes	Yes	Yes
Slovak Republic	Yes	Yes	Yes	Yes	Partial	Yes
Slovenia	Yes	Yes	Yes	Yes	Partial	Partial
Spain	Yes	Yes	No	Yes	No	No
Sweden	Yes	Yes	Partial	Yes	Yes	Yes

profession that is identified and/or regulated at Member State level rather than at EU level albeit with overlapping qualifications frameworks that meet requirements of the European Qualifications Framework. In support of a unified approach to proposing a Common Training Framework EFLM's affiliated societies adopted the term '*Specialist in Laboratory Medicine*' as the unifying descriptor of specialist practice amongst medical, scientific and pharmacy trained professionals in 2012 [8]. Whilst not intended as a precursor to identifying a newly regulated profession at EU Level the name forms the central descriptor within a Common Training Framework.

## 4 The shape of a Common Training Framework

### 4.1 An equivalence of standards of practice amongst the EU member states

EFLM's Equivalence of Standards distinguish the specialist practitioner in laboratory medicine from the non-specialist. Based on the principles of the 1999 Bologna process [9] the key elements of the standards:

- Defines 9 (preferably 10) years as minimum training period with a Master of Science (MSc or equivalent) qualification after an initial 4 to 5-year academic period followed by an EFLM-approved exit qualification/certificate after a further 4 years vocational training.
- Includes expectations for education and training to follow the EFLM syllabus [10] that also identifies the competences 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

Based on the requirements in which the profession and/or its training is regulated the training content should include:

- 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, genetics and In Vitro Fertilisation in a proportion consistent with the requirements in the country of destination, consisting

**Table 2:** The professional profile of non-medical specialists in Laboratory Medicine across the European Union. Member States able to meet expectations of EFLM's proposed Common Training Framework are highlighted in green.

	Predominant non-medical specialist practitioner	Meets EFLM equivalence of standards	Professional regulation and/or regulated training in place	Professional title
Austria	Not applicable			
Belgium	Pharmacist	Yes	Yes	Pharmacien biologiste (Pharmacist biologist)
Bulgaria	Scientist	Yes	Yes	Специалист по клинична химия (Specialist in clinical chemistry)
Croatia	Scientist	Yes	Yes	Specijalist medicinske biokemije i laboratorijske medicine (Specialist in medical biochemistry and laboratory medicine)
Cyprus	Scientist	Yes	Yes	ΔΙΕΥΘΥΝΤΗΣ ΚΛΙΝΙΚΟΥ ΕΡΓΑΣΤΗΡΙΟΥ (DIEFTHINTIS KLINIKOU ERGASTIRIOU (Clinical Laboratory Director)
Czech Republic	Scientist	Yes	Yes	Bioanalytik pro klinickou biochemii (Bioanalyst for Clinical Chemistry)
Denmark	Scientist	Yes	No	Biokemiker (Biochemist)
Estonia	Scientist	No	No	Laborispetsialist (Laboratory specialist)
Finland	Scientist	Yes	Yes	Sairaalakemisti (Clinical biochemist)
France	Pharmacist	Yes	Yes	Pharmacien biologiste (Pharmacist biologist)
Germany	Scientist	Yes	No	Fachwissenschaftler Labordiagnostik (Biomedical scientist)
Greece	Scientist	Yes	No	Κλινικός Χημικός/Κλινικός Βιοχημικός (Clinical chemist/ clinical biochemist)
Hungary	Scientist	Yes	Yes	Klinikai biokémikus (Clinical biochemist)
Ireland	Scientist	Yes	No	Clinical biochemist
Italy	Scientist	Yes	Yes	Specialista in Patologia clinica e Biochimica clinica (Specialist in Clinical Pathology and Clinical Biochemistry)
Latvia	Scientist	No	Yes	Laboratorijas specialisti (Laboratory Specialist)
Lithuania	Scientist	Yes	Yes	Medicinos biologas (Medical biologist)
Luxembourg	Pharmacist			
Malta	Not applicable			
Netherlands	Scientist	Yes	No	Specialist klinische chemie (Specialist in clinical chemistry)
Poland	Scientist	Yes	Yes	Specialist in Laboratory Diagnostics
Portugal	Pharmacist	Yes	Yes	Especialista em Análises Clínicas (Clinical Analysis Specialist)
Romania	Scientist	Yes	No	Biochimist, Biolog sau Chimist in sistemul sanitar (Biochemist, Biologist or Chemist in the health system)
Slovak Republic	Scientist	Yes	Yes	Laboratórny Diagnostik Specialista (Specialist in Laboratory Diagnostics)
Slovenia	Scientist	Yes	Yes	Specialist medicinske biokemije (Specialist in Medical Biochemistry)
Spain	Pharmacist	Yes	Yes	Especialista (Specialist) Médico, Farmacéutico, Químico o Biólogo (Medical, Pharmaceutical, Chemist or Biologist)
Sweden	Scientist	No	No	Sjuknuskemist (Clinical biochemist)

of work experience, accredited courses, relevant exams of the national training programs, traineeships.

The elements of training in the main fields of laboratory include:

- General chemistry: general biochemistry and pathophysiology, endocrinology, oncology, cardiovascular, metabolic, renal and other biomarkers, humoral immunology, therapeutic drug monitoring and toxicology.

- Haematology: cytometry, haemostasis, cellular immunology and transfusion medicine.
- Microbiology includes bacteriology, mycology, virology, parasitology and emerging diseases that affect public health.

In addition, elements of sub-specialisation may include:

- Genetics includes molecular diagnostics
- IVF includes fertility testing, semen investigation, semen preparation and *in vitro* fertilization.

## 4.2 The expected base of knowledge, skills and competences

Throughout training and education, the objective is to develop the knowledge, skills, competence, attitudes and behaviours consistent with specialist level clinical, scientific and professional practise. The key elements of the 2018 EFLM syllabus [10] include:

- Generic knowledge, skills and competences
  - Basic knowledge requirements
  - Indications for laboratory medicine procedures
  - Influence of collection and storage of specimens
  - Analytical principles and techniques;
  - Reference methodology
  - Evaluation and assessment
  - Case related medical evaluation of laboratory tests
  - Clinical training
- Specialist knowledge within each discipline.
  - General chemistry
  - Haematology
  - Microbiology
  - Genetics, genomics and cytogenetics
  - In vitro fertilisation
- Skills and competences required to carry out research, development and audit.
- Leadership skills and competences.
  - Laboratory direction and leadership
  - Laboratory organisation and management
  - Quality assurance
  - Education/training/continuous professional development
  - Laboratory health and safety, management of waste
  - Legal, ethical and governance considerations
  - Professional practice and soft skills

## 4.3 An expected code of conduct [11]

The code of conduct behoves specialists to conduct themselves in a manner that does not bring into disrepute the discipline and the profession of Clinical Chemistry and

Laboratory Medicine. They shall value integrity, impartiality and respect for persons and evidence and shall seek to establish the highest standards of quality and ethics in their work. Because of their concern for valid evidence, they shall ensure that research is carried out in keeping with the highest standards of scientific integrity. Taking

account of their obligations under the law, they shall hold the interest and welfare of patients and those in receipt of their services to be paramount at all times and ensure that the interests of participants in research are safeguarded. All registrants agree to abide by this Code of Conduct. They are also obliged to comply with the Codes of Conduct of their appropriate national registration body and national societies, where appropriate. If a specialist is subject to disciplinary sanction (e.g. suspension, removal from their national register), EFLM applies the same outcome in relation to the EFLM Register.

## 5 Discussion

In line with three key conditions of the Professional Qualifications Directive that need to be fulfilled for being subject to a Common Training Framework, non-medical specialists:

- a) can be identified as a regulated profession and/or a profession whose training is regulated in at least one third (33%) of the EU member states,
- b) are not already subject to automatic recognition as a sectorial profession nor to another level Common Training Framework
- c) would possibly have their professional mobility enhanced with the adoption of a Common Training Framework

The proposed Common Training Framework builds on EU guidance [12] for a ‘bottom up’ approach in which professional organisations or competent authorities from at least one third of the Member States may submit suggestions for a framework to the Commission. Such an approach is meant to ensure that proposals respond to real needs felt by the profession and benefit from the in-depth knowledge and understanding of the area concerned. At the time of writing 19 of EFLM’s affiliated national societies in the EU highlight their country’s ability to meet the federation’s Equivalence of Standards, the expected level of knowledge, skill and competency, and the code of conduct. Amongst these 19 Member States 15 (53%) are also able to meet the requirements of the proposed Common Training Framework in that the profession and/or training is regulated and their national qualification frameworks are formally linked (referenced) to the European Qualifications Framework for lifelong learning [13], a further EU Commission requirement for submission of the framework.

In progressing a submission the opportunity arises for the EU Commission to adopt a Common Training Framework by “delegated act” (a delegation granted in the text

of an EU law such as the Professional Qualifications Directive that allows consideration of a suggested framework by delegated authorities within the Commission) followed by an implementing act to list the national professional qualifications and national titles that benefit from automatic recognition under the adopted Common Training Framework [14]. However, whilst laboratory medicine has established key building blocks for the mutual recognition of its specialist practitioners' qualifications a current 'a priori' challenge across the EU is determining the 'proportionality' of the professional regulatory frameworks held within the individual member states which may have been built up and/or modified over many years [15]. The uneven scrutiny of the regulation of professions across the EU has been deemed to have a negative impact on the provision of services and the mobility of professionals in a single EU market - the need for a mutual evaluation exercise facilitated by the Commission was identified within EC Directive 2013/55/EC to ensure greater transparency and justification [16]. Within the exercise Member States provide a list of their regulated professions, the activities reserved for them and a justification of the need for regulation. The subsequent 2018 Proportionality Directive [17] supplements provisions within the 2013 Directive and now requires Member States to review existing regulations of professions or when proposing new ones.

## Conclusions

Through the engagement of professional organisations 15 EU Member States have been identified as candidate signatories to a Common Training Framework for *Specialists in Laboratory Medicine*. Achieving recognition is an ongoing project in part dictated by external timelines and jurisdictions but crucially also by professional organisations and competent authorities who recognise the catalytic effect the Professional Qualifications Directive brings to harmonising the education and training that enhances patient safety when professionals migrate across country borders. Whilst Common Training Frameworks do not replace national programmes unless a Member State decides otherwise [5] it is of note that the EFLM syllabus has been adopted as the template for education and training in 19 Member States. Pending progress with achieving proportionate professional regulation and further guidance from the EU Commission the onus is on national societies and

competent authorities to capitalise on opportunities to submit suggestions for a Common Training Framework as and when they arise. EFLM's proposed framework carries the support of more than one third of its professional organisations in the EU Member States. In turn the framework supports and contributes to the Directive's enabling goals for increasing professional mobility, enhancing patient safety and ensuring a more equitable distribution of skills and expertise across the Member States.

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