Review

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Laboratory medicine in the European Union

Abstract: The profession of laboratory medicine differs between countries within the European Union (EU) in many respects. The objective of professional organizations of the promotion of mutual recognition of specialists within the EU is closely related to the free movement of people. This policy translates to equivalence of standards and harmonization of the training curriculum. The aim of the present study is the description of the organization and practice of laboratory medicine within the countries that constitute the EU. A questionnaire covering many aspects of the profession was sent to delegates of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) and Union Européenne de Médecins Spécialistes (UEMS) of the 28 EU countries. Results were sent to the delegates for confirmation. Many differences between countries were identified: predominantly medical or scientific professionals; a broad or limited professional field of interest; inclusion of patient treatment; formal or absent recognition; a regulated or absent formal training program; general or minor application of a quality system based on ISO Norms. The harmonization of the postgraduate training of both clinical chemists and of laboratory physicians has been a goal for many years. Differences in the organization of the laboratory professions still exist in the respective countries which all have a long historical development with their own rationality. It is an important challenge to harmonize our profession, and difficult choices will need to be made. Recent developments with respect to the directive on Recognition of Professional Qualifications call for new initiatives to harmonize laboratory medicine both across national borders, and across the borders of scientific and medical professions.

Keywords: directive; European Federation of Clinical Chemistry and Laboratory Medicine (EFLM); European Union (EU); harmonization; training; Union Européenne de Médecins Spécialistes (UEMS).

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Introduction

The profession of clinical chemistry and laboratory medicine is practiced in all countries in Europe. This profession however, differs between countries in many respects, such as background training, fields of interest, legal status and professional organization.

There are two European organizations that represent national professional organizations in the field of Clinical Chemistry: European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) and the Union Européenne de Médecins Spécialistes (UEMS), Section of Laboratory Medicine/Medical Biopathology. Both have an important objective to promote mutual recognition of laboratory specialists within the European Union (EU). This is closely related to the free movement of people, a major goal of European integration. This policy translates to equivalence of standards and harmonization of the training curriculum, both the central tasks of the European professional organizations.

The aim of the present study is the description of the organization and practice of clinical chemistry and laboratory medicine within the countries that constitute the EU. This might serve to achieve a better understanding of the profession in the process of harmonization.

Materials and methods

In 2010 the UEMS and EFCC (now EFLM) decided to jointly start this project to investigate the situation of the profession of clinical chemistry within the EU. A questionnaire was developed with open questions about different aspects of the profession: the naming of the profession, fields of interest, number of specialists, number of laboratories,

professional organizations, and differences between scientific and medical trained specialists, organization of training and accreditation of laboratories. An explanation of the aim of each question was included.

The questionnaire was sent to delegates of both EFCC and UEMS of the 28 EU countries that are a full member of the EU (Table 1). Uncertainties and omissions were communicated with the respondents and discussed by e-mail. A standardized abstract of the questionnaire was sent to the delegates for confirmation. Local changes during the time of this study were included in the results.

Results

Out of the 28 countries, all responded except Malta, Latvia and Luxembourg (Table 1). Malta and Luxembourg do not have a training program in their county.

Definition of the specialty

Many different names are used for the specialty field at a national level (Table 1), which is reflected in the EC directives [1, 2]. The words used in different combinations are:

Table 1 Names of specialties and EFLM/IFCC member societies in the European Union countries.

EU countries	Name specialty	Name professional society (member EFLM) (4,5)
1. Austria	Medizinische und Chemische Labordiagnostik	Österreichische Gesellschaft für Laboratoriumsmedizin und Klinische Chemie (ÖGLKMC)
2. Belgium	Biologie Clinique; Klinische Biologie	Société Royale Belge de Chimie Clinique, Belgische Vereniging voor Klinische Chemie (KBVKC, SRBCC)
3. Bulgaria	клинична лаборатория (Clinical Laboratory)	Bulgarian Society of Clinical Laboratory
4. Croatia	Specijalist Medicinske Biokemije i Laboratorijske Medicine	Hrvatsko društvo za medicinsku biokemiju i laboratorijsku medicinu (HDMBLM)
5. Cyprus	ΚΛΙΝΙΚΟΣ ΧΗΜΙΚΟΣ (Clinical Chemistry)	Association of Clinical Laboratory Directors, Biomedical and Clinical Laboratory Scientists (ACLDBCLS)
6. Czech Republic	Klinická Biochemie	Česká společnost klinické biochemie (ČSKB)
7. Denmark	Klinisk Biokemi	Dansk Selskap for Klinisk Biokemi (DSKB)
8. Estonia	Laborimeditsiin	Eesti Laborimeditsiini Ühing (ESLM)
9. Finland	Kliininen Kemia Sairaalakemisti	Suomen Kliinisen Kemian Yhdistys (SKKY)
10. France	Biologie Médicale	Societé Francaise de Biologie Clinique (SFBC)
11. Germany	Laboratoriumsmedizin	Deutsche Vereinte Gesellschaft für Klinische Chemie und Laboratoriumsmedizin e.V. (DGKL)
12. Greece	Κλινική Χημεία-Κλινική Βιοχημεία	Greek Soc.Clin. Chem.Clin. Biochem. (EEKX-KB)
13. Hungary	Orvosi Laboratóriumi Diagnosztika	Magyar Laboratóriumi Diagnosztikai Társasag (MLDT)
14. Ireland	Clinical Biochemistry, Clinical Chemistry	Association of Clinical Biochemists in Ireland (ACBI)
15. Italy	Biochimica Clinica	Società Italiana di Biochimica Clinica e Biologia Molecolare Clinica (SIBIOC)
16. Latvia	Laboratora Medicına	Latvijas Laboratorijas Specialistu biedriba (LSB)
17. Lithuania	Laboratorine Medicine	Lithuanian Society Laboratory Medicine
18. Luxembourg	Biologie Clinique/Biochemie	Societé Luxembourgeoise de Biologie Clinique (SLBC)
19. Malta	Patologija Kimika	–
20. Netherlands	Klinische Chemie	Nederlandse Vereniging voor Klinische Chemie en Laboratorium Geneeskunde (NVKC)
21. Poland	Laboratoryjna Diagnostyka Medyczna	Polskie Towarzystwo Diagnostyki Laboratoryjnej (PTDL)
22. Portugal	Análises Clínicas (PharmD); Patologia Clínica (MD)	Sociedade Portuguesa de Química Clínica (SPQC)
23. Romania	Medicina de Laborator	Societatea Romana de Medicina de Laborator (SRLM)
24. Slovak Republic	Laboratórna medicína/Klinickej biochémie	Slovenská spoločnost' pre laboratórnu medicínu (SSLM)
25. Slovenia	Medicinska Biokemija	Slovensko Združenje za Klinično Kemijo (SZKK)
26. Spain	Bioquímica Clínica (monovalent), Análisis clínicos (polyvalent)	Sociedad Española de Bioquimica Clinica y Patolgía Molecular (SEQC)
27. Sweden	Klinisk Kemi	Svensk Förening för Klinisk kemi (SFKK)
28. UK	Clinical Biochemistry/Chemical Pathology	The Association for Clinical Biochemistry and Laboratory Medicine (ACB)

clinical, medical, laboratory, (bio)chemistry and diagnostic. Together these words accurately define the profession of clinical chemistry and laboratory medicine. At the European level, the EFCC (now named EFLM) in 2010 has adopted the name of the profession "specialist in laboratory medicine", after consultation of and voting by the National Societies [3].

Professional societies

The EFLM member societies are listed in Table 1 [4, 5]. Except for Cyprus and (until recently) Croatia, all these professional societies are mixed, with members of both scientific and medical background. About half of the countries reported a separate professional organization exclusively for members of medical background (Cyprus, Czech Republic, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Portugal, Slovakia, Spain and UK).

Number and background of specialists (Table 2)

The academic training before specialization varies between EU countries. All countries have specialists of both medical and scientific background, with medical laboratory professionals being officially recognized as medical specialists. The Netherlands is an exception, where the training of medical specialists was stopped in 2001. In Croatia the medical specialty of laboratory medicine was recently started upon entering the EU. The proportion of medical doctors varies between countries, with at the low end Croatia (0%) and the Netherlands (8.1%), and at the high end Greece (92%) and Austria, that does not have laboratory specialists with a scientific background. The total number of laboratory specialists in the EU is (with background): 14,800 (physicians), 11,300 (pharmacists), and 10,200 (scientists). Medical specialists in laboratory medicine thus comprise around 40% of more than 30,000 practicing laboratory professionals in the EU.

In five countries pharmacists constitute a high proportion of the laboratory professionals: France (73%), Spain (61%), Portugal (57%), Slovenia (50%) and Belgium (45%). Except for Slovenia, these countries have a training that is almost exclusively restricted to medical doctors and pharmacists. In France both groups have an equal legal position. All other counties, however, have few pharmacists in clinical chemistry. The mean proportion of pharmacists in these 19 countries is 2.1% (range 0%–9.5%). Their training and position is in most cases equal to scientists but not to medical doctors.

The total number of laboratory specialists differs considerably between the EU countries. Expressed as the number of laboratory specialists per inhabitant, Greece has the highest number with 346 per million, followed by Cyprus with almost 200 per million. At the low end are Ireland and the UK with 4.2 and 11.6 per million, respectively. The countries are different with regard to the number of fields of interest that are part of the laboratory medicine specialty. If we take into account six specialized fields [biochemistry, hematology, endocrinology, immunology, transfusion medicine (serology) and microbiology], there is only a weak correlation between the number of laboratory specialists, and the number of specialized fields of the profession.

Academically trained laboratory professionals (Master's degree) without specialist training do exist in some countries. In the UK these are named "*biomedical scientist*". In Croatia, more than half of the people who have studied clinical chemistry find work in the laboratory without further post-academic specialization (280 vs. 249 specialists).

By exception, in some countries technologists have university level training. In Sweden technicians working in the laboratory have a 3-year university degree to become a "*licensed practitioner of medicine*". They do not have the level of training to carry out the same responsibilities as a clinical chemist, and are not accepted in the EC4 Register [6].

Fields of interest and responsibilities in clinical chemistry/laboratory medicine (Table 3)

Laboratory medicine does include different fields in different countries. "*Laboratoriumsmedizin*" in Germany and Austria includes biochemistry, endocrinology, microbiology and hematology and transfusion medicine. This form of general laboratory medicine (however with a special position of transfusion medicine) is practiced in other countries like France and Spain (*análisis clinicos*). Hematology is only practiced by physicians in Spain, as the specialty includes clinical practice and blood transfusion. However, *clinical biochemistry* in the UK does not include hematology and microbiology. In most cases, however, the medical laboratory profession in this country (*chemical pathology*) includes the treatment of outpatients (lipid clinics, metabolic disorders etc.).

Laboratory medicine is sometimes called "polyvalent" or "general" if it includes a broad field of interests, and "monovalent" if it includes only one field of interest

Table 2 Number of laboratory specialists and academic training.

Countries	Inhabitants (million)	Laboratory specialists (number)	Laboratory specialists per million inhabitants	Medical, %	Pharmacists, %	Scientists, %
1. Austria	8.2	302	36.8	78.5	0	21.5[a]
2. Belgium	10.4	925	85.6	54.4	44.5	0.0
3. Bulgaria	7.9	405	51.3	74.1	1.2	24.7
4. Croatia	4.3	249	57.9	0	0	100
5. Cyprus	0.80	159	199	18.2	0	81.8
6. Czech Republic	10.2	690	67.6	37.7	4.3	58.0
7. Denmark	5.5	142	25.8	53.5	8.5	38.0[a]
8. Estonia	1.29	172	133	49.4	0	50.6[a]
9. Finland	5.2	278	53.5	31.7	0	68.3
10. France	61.4	11,000	179	27.0	73.0	0.0
11. Germany	82.3	2102	25.5	67.7	0	32.4
12. Greece	11.0	3800	346	92.1	0	7.9
13. Hungary	9.9	431	43.5	52.5	12.5	35.0
14. Ireland	4.2	19	4.2	52.6	0	88.9
15. Italy	57.1	5900	103	33.9	1.7	64.4
16. Latvia	2.2	–	–	–	–	–
17. Lithuania	3.6	250	78.1	20.0	0	80.0
18. Luxembourg	0.49	–	–	–	–	–
19. Malta	0.40	–	–	–	–	–
20. Netherlands	16.5	245	16.5	8.1	1.8	90.1
21. Poland	38.2	1265	33.1	9.1	9.5	83.0
22. Portugal	10.7	1743	163	42.9	57.1	0.0
23. Romania	22.2	2320	105	34.5	0.9	64.7
24. Slovak Republic	5.5	510	92.7	38.8	0	61.2
25. Slovenia	2.0	72	36.0	2.8	48.6	48.6
26. Spain	46.7	2450	53.3	28.6	61.2	10.2
27. Sweden	9.1	243	26.7	54.7	0	45.3[a]
28. UK	60.6	700	11.6	28.6	0	71.4

[a]There is no formal specialization for scientists in laboratory medicine. They can work in a laboratory according to their particular special competence but they do not become specialists.

(e.g., microbiology, transfusion medicine). We arbitrarily define laboratory medicine here as polyvalent or general, if it includes at least biochemistry, hematology and microbiology. According to that definition, 60% (15/25) of the countries included in this study are polyvalent (Table 3). This corresponds to 83% of all laboratory specialists in the EU working in countries with a polyvalent or general type of laboratory medicine.

Responsibilities of medical and scientific laboratory specialists (Table 4)

There are differences in professional responsibilities between medical and scientific laboratory specialists in European countries. In the Netherlands, clinical chemists with a scientific background can be responsible for all aspects of clinical chemistry, including transfusion medicine. In contrast, clinical chemists in Germany cannot operate but under the responsibility of a laboratory physician or another medical doctor.

The limited responsibilities of laboratory specialists with a scientific background compared to physicians concern the responsibility for diagnosis and patient treatment advice to the clinician, or the end-responsibility of the laboratory work.

In most countries both physicians, pharmacists and laboratory specialists with scientific background can be the head of a laboratory. Sometimes this is restricted to upper grade specialists (UK: consultant level). Most countries, however, do not have different grades.

Pharmacists were reported to have less limitations with respect to responsibilities compared to physicians (not limited 11, limited 4, not applicable 10), than specialists with a scientific background (not limited 14, limited 9, not applicable 2) (Table 4).

Table 3 Laboratory medicine and fields of interest.

	Biochemistry	Endocrinology	Immunology	Hematology	Transfusion	Microbiology
1. Austria	Yes	Yes	Yes	Yes	Yes	Yes
2. Belgium	Yes	Yes	Yes	Yes	Yes	Yes
3. Bulgaria[a]	Yes	Yes	Yes	Yes	No	No
4. Croatia	Yes	Yes	Yes	Yes	No	No
5. Cyprus[b]	Yes	Yes	Yes	Yes	Part	Yes
6. Czech Republic	Yes	Yes	Part	Yes	No	No
7. Denmark	Yes	Yes	Yes	Yes	No	No
8. Estonia[a,e]	Yes	Part	No	Yes	Yes	No
9. Finland	Yes	Yes	Part	Yes	Yes	Part
10. France	Yes	Yes	Yes	Yes	Yes	Yes
11.Germany	Yes	Yes	Yes	Yes	Yes[b]	Yes[b]
12. Greece[f]	Yes	Yes	Yes	Yes	Yes	Yes
13. Hungary[a,c,f]	Yes	Yes	Yes	Yes	No	Yes
14. Ireland	Yes	Yes	Part	No	No	No
15. Italy	Yes	Yes	Yes	Yes	No	Yes
16. Latvia	–	–	–	–	–	–
17. Lithuania	Yes	Yes	Yes	Yes	Part	Yes
18. Luxembourg	–	–	–	–	–	–
19. Malta	–	–	–	–	–	–
20. Netherlands	Yes	Yes	Yes	Yes	Yes	No
21. Poland	Yes	Yes	Yes	Yes	Part	No
22. Portugal	Yes	Yes	Yes	Yes	Part	Yes
23. Romania	Yes	Yes	Yes	Yes	yes	Yes
24. Slovak Republic	Yes	Yes	Yes	Yes	Part	Yes
25. Slovenia	Yes	Yes	Yes	Yes	No	Part
26. Spain[d]	Yes	Yes	No	Yes	No	Yes
27. Sweden	Yes	Yes	Part	Yes	No	No
28. UK	Yes	Yes	No	No	No	No

Part: some laboratories perform these tests, or only in part (e.g., routine tests); only transfusion serology (Slovak Republic); MD, medical doctor; Pharm, Pharmacist; Sc, Scientist. [a]hematology by MD (Estonia: laboratory hematology); [b]only by MD; [c]Hungary: immunology by MD; [d]In Spain Bioquímica clínica (monovalent): endocrinology, immunology; Análisis clínicos (polyvalent): hematology, microbiol. (MD); [e]transfusion by laboratory hematology (MD); [f]microbiology by MD.

Specialist training and registration

The EC4 curriculum [6] was used in 16 countries in the development of the local specialist training curriculum. It was reported to be background information (Finland, Lithuania), or was even identical to EC4 curriculum (France). In the UK there is a close overlap between EC4 and the national curriculum, where the UK curriculum predates that of EC4. In most countries the EC4 curriculum was used for training of scientists or pharmacists, with the exception of six countries (Bulgaria, Estonia, France, Hungary, Lithuania and Slovenia) where it was also used in training of medical specialists.

The UEMS curriculum [7] was used in less countries for the medical training: Finland, Hungary, Portugal and Slovakia. Sweden has a special position, as the UEMS curriculum was adapted based on the Swedish situation.

The duration of the training was calculated as the number of years after completion of the university training. In some countries, there is an obligatory pre-training period, before the training can be started. This period was interpreted to be part of the total specialist training period (Table 5). Some countries have an academical study in clinical chemistry (Croatia and other Balkan countries not included in the EU). Only this study allows trainees to enter the specialist training. In Croatia, about 50% of these academics choose not to do this specialization, and work in clinical laboratories with a limited responsibility.

There is no training of laboratory specialists in Cyprus. It has a system of certificates (after 1 year training) in subspecialties hematology, biochemistry, immunology and microbiology. Diplomas from abroad are accepted after a validation procedure. Training predominantly takes place in Greece. Malta and Luxembourg do not to have specialist training.

For scientists, there is no formal training in four countries (excluding countries with only physicians and pharmacists): Austria, Estonia, Denmark and Sweden.

Table 4 Position of scientists and pharmacists compared to physicians.

	Scientist	Pharmacist
1. Austria	Limited	NA[a]
2. Belgium	NA[a]	Not limited
3. Bulgaria	Limited	limited
4. Croatia	Not limited	NA[a]
5. Cyprus[a]	Not limited	NA[a]
6. Czech Republic	Not limited	Not limited
7. Denmark	Limited	Limited
8. Estonia	Limited	Limited
9. Finland	Limited	NA[a]
10. France	NA[a]	Not limited
11. Germany	Limited	NA[a]
12. Greece	Limited[b]	NA[a]
13. Hungary	Limited	Limited
14. Ireland	Not limited	NA[a]
15. Italy	Not limited	Not limited
16. Latvia	–	–
17. Lithuania	Not limited	NA[a]
18. Luxembourg	–	–
19. Malta	–	–
20. Netherlands	Not limited	Not limited
21. Poland	Not limited	Not limited
22. Portugal	Limited[c]	Not limited
23. Romania	Not limited	Not limited
24. Slovak Republic	Not limited	Not limited
25. Slovenia	Not limited	Not limited
26. Spain	Not limited	Not limited
27. Sweden	Limited	NA[a]
28. UK	Not limited	NA[a]

NA, not applicable; [a]No specialists, or very limited number; [b]only MD can be end responsible in private laboratory; [c]Not allowed to assume the position of technical director of a laboratory.

Re-registration is obligatory for laboratory physicians in eight countries (9/25, 36%) (Table 5). Re-registration can be linked to a financial stimulus (health insurance reimbursement), while not connected to the losing of registration (Belgium). For specialists with a scientific background, re-registration is obligatory in 11 out of 23 countries (48%). In the 14 countries with a relevant number of pharmacists, nine had a re-registration program (64%).

There was a continuous medical education (CME) program in place in 20 out of 25 countries (80%) (Table 6). In some countries the system is only for physicians (Austria, Germany).

Organization and responsibility of training

The official recognition of the profession of laboratory specialists differs between EU countries. In all countries, the medical laboratory specialty is acknowledged by law, with an official register regulated by the official medical council and/or under responsibility of the ministry of health. For professionals with a scientific background, there was not (or not yet) a register in all countries. There is a register in 16 countries, and no register in seven countries.

From the data it was not always clear, whether the organization holding the register of scientists was private, or officially recognized. In one country (France) it is not applicable, with only physicians and pharmacists admitted to the profession. Pharmacists are recognized in all countries with substantial numbers of specialists with this background training, with the exception of Denmark, where there is only a formal training for physicians.

Accreditation ISO/EN 15189

Quality is a central issue for laboratory profession, and the development of a quality system based on ISO/EN15189 has taken place in many laboratories in the EU. Also in this field there are large differences between countries. Some countries have reached an almost complete introduction of audits and accreditation: Sweden, Finland, The Netherlands, and France, where this is now compulsory by law. Other countries are still at the beginning of this development (Table 6). In some countries ISO 9000 is used – for the time – more predominantly than ISO 15189 (Austria, Italy) and can be obliged by health insurance (Italy).

Although the ISO 15189 is not compulsory by law in Germany, there is a legal regulation called "*Richtlinien der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen (RiliBÄK)*" which has adopted essential contents of ISO 15189, particularly quality management aspects and management of documents. Therefore, parts of ISO 15189 are also obligatory in Germany.

Discussion

Clinical chemistry and laboratory medicine was defined by the IFCC as the application of chemical, molecular and cellular concepts and techniques to the understanding and the evaluation of human health and disease. At the core of the discipline is the provision of results of measurements and observations, together with interpretation and informed clinical advice relevant to the maintenance of health, the cause of disease, the diagnosis of disease, predicting and monitoring the response to therapy, and

Table 5 Duration of training, registration and re-registration.

Countries	Duration of training			Examination			Registration			Re-registration		
	MD	Sc	Pharm	MD	Sc	Pharm	MD	Sc	Pharm	MD	Sc	Pharm
1. Austria	6	NA[a]	NA[b]	Y	N	NA[b]	Y	N	NA[b]	N	N	NA[b]
2. Belgium	5	NA[b]	5	N	NA[b]	N	Y	NA[b]	Y	N[g]	NA[b]	N[g]
3. Bulgaria	4	3	NA[b]	Y	Y	NA[b]	Y	N	NA[b]	N	N	NA[b]
4. Croatia	4[h]	4	NA[b]	NA[b]	y	NA[b]	Y	Y	NA[b]	Y	Y	NA[b]
5. Cyprus	NA[c]	NA[c]	NA[b]	NA[c]	NA[c]	NA[b]	Y	Y[i]	NA[b]	N	N	NA[b]
6. Czech Republic	5	5	5	Y	Y	Y	Y	Y	Y	Y	Y	Y
7. Denmark	6.5	5[a]	5[a]	N	N	N	Y	N	N	N	N	N
8. Estonia	4	NA[a]	NA[b]	Y	N	NA[b]	Y	N	NA[b]	N	N	NA[b]
9. Finland	6	5	NA[b]	Y	Y	NA[b]	Y	Y	NA[b]	N	N	NA[b]
10. France	6	NA[b]	6	Y	2	Y	Y	NA[b]	Y	Y	NA[b]	Y
11. Germany	5	5	NA[b]	Y	N	NA[b]	Y	Y	NA[b]	N	N	NA[b]
12. Greece	5	5[h]	4[h]	Y	9	NA	Y	Y	y	N	Y	y
13. Hungary	5	4	5	Y	Y	Y	Y	Y	y	Y	Y	y
14. Ireland	7[d]	7[d]	NA[b]	Y	Y	NA[b]	Y	Y	NA[b]	Y	N	NA[b]
15. Italy	5	5	5	N	N	N	Y	N	N	N	N	n
16. Latvia	–	–	–	–	–	–	–	–		–	–	–
17. Lithuania	4	2[e]	NA[b]	Y	N	NA[b]	Y	N	NA[b]	N	N	NA[b]
18. Luxembourg	NA[c]	NA[c]	NA[c]	NA[c]	NA[c]	NA[c]	–	–	–	–	–	–
19. Malta	NA[c]	NA[c]	NA[c]	NA[c]	NA[c]	NA[c]	–	–	–	–	–	–
20. Netherlands	NA[c]	4	4	NA	Y	Y	Y	Y	Y	NA[c]	Y	Y
21. Poland	4	4	4	Y	Y	Y	Y	Y	Y	N	N	N
22. Portugal	5	4	4	Y	Y	Y	Y	Y	Y	N	Y	Y
23. Romania	5	5[a]	5[a]	Y	Y	Y	Y	Y	Y	Y	Y	Y
24. Slovak Republic	6	5	5	Y	Y	Y	Y	Y	Y	Y	Y	Y
25. Slovenia	5[f]	5[f]	5[f]	Y	Y	Y	Y	Y	Y	Y	Y	Y
26. Spain	4	4	4	N	N	N	Y	Y	Y	N	N	N
27. Sweden	5	NA[a]	NA[b]	N	N	NA[b]	Y	N	NA[b]	N	N	NA[b]
28. UK	5[d]	5	NA[b]	Y	Y	NA[b]	Y	Y	NA[b]	Y	Y	NA[2]

NA, not applicable; MD, medical doctor; Pharm, pharmacist; Sc, scientist. [a]no formalized training, training "on the job"; [b]no specialists, or very limited number; [c]no training available; [d]duration of training not fixed, 2–3 years pre-registration (before master degree), 5 years post-registration; [e]additional training will be introduced; [f]Four years specialization after 1 year with state examination; [g]not obligatory, but stimulated with financial bonus; [h]training recently started [8]; [i]voluntary.

follow-up investigations. The discipline is committed to deepening the understanding of health and disease through fundamental and applied research [9].

Notwithstanding the clear definition of the field of interest, many differences exist between countries with respect to a wide variety of aspects of the profession. Harmonization has been an important objective, and has a long history. In 1958 – one year after the treaty of Rome was signed – the representatives delegated by the professional organizations of medical specialists of the six member countries of the very new European Community (EEC), who met in Brussels, created the European Union of Medical Specialists [Union Européenne des Médecins Spécialistes (UEMS)]. The main objectives of the UEMS are: to promote the highest level of training of the medical specialists, medical practice and health care within the EU and to promote free movement of specialist doctors within the EU. The UEMS represents the medical specialist profession in the member states of the EU, to EU authorities and any other authority dealing with questions concerning the medical profession.

In 1988 the FESCC was founded, joining the different national societies for clinical chemistry and laboratory medicine. The harmonization and recognition of laboratory specialists, particularly of scientific and pharmaceutical background, was the main objective from the start. The EC4 was founded, with the goal to harmonize the training and establishing a European register for highly trained specialist, whatever their background.

Between European countries there are many differences: predominantly medical or scientific professionals; an important proportion of pharmacists or a negligible number; a broad professional field of interest including many aspects of laboratory medicine, or a more limited

Table 6 Registration, examination and ISO 15189 accreditation.

Countries	Official recognition		ISO 15189	CME system
	MD	Sc	Accreditation	
1. Austria	Y	N	<5%[b]	Y[g]
2. Belgium	Y	Y	75%[c]	Y
3. Bulgaria	Y	Y	0%	N
4. Croatia	Y	Y	<5%	Y
5. Cyprus	Y	Y	10%	N
6. Czech Republic	Y	Y	40%	Y
7. Denmark	Y	N	30%	N
8. Estonia	Y	N	33%	Y
9. Finland	Y	Y	90%[d]	Y[h]
10. France	Y	NA[a]	3.2%	Y
11. Germany	Y	N	25%[e]	Y[g]
12. Greece	Y	N	1%	Y
13. Hungary	Y	Y	<5%	Y
14. Ireland	Y	Y	75%	Y
15. Italy	Y	Y	<5%[f]	Y
16. Latvia	–	–	–	–
17. Lithuania	Y	Y	<5%	n
18. Luxembourg	–	–	–	–
19. Malta	–	–	–	–
20. Netherlands	Y	N	>90%	Y
21. Poland	Y	Y	3–5%	Y
22. Portugal	Y	Y	15%[b]	Y
23. Romania	Y	Y	30%	Y
24. Slovak Republic	Y	Y	20%	Y
25. Slovenia	Y	Y	0%	Y
26. Spain	Y	Y	0.5%	Y[i]
27. Sweden	Y	N	100%	N
28. UK	Y	Y	94%	Y

NA, not applicable; CME, continuous medical education; MD, medical doctor; Sc, scientist. [a]no specialists, or very limited number; [b]few ISO 15189, majority ISO 9000/9001; [c]estimated; [d]90% large laboratories, 15% small laboratories; [e]private 90%, hospital 5%, total number is estimate; [f]linked to insurance, most ISO 9000/9001; [g]only for physicians; [h]connected with accreditation according to ISO 15189; [i]CME used for professional and economical recognition within an institution.

specialized field; inclusion of patient treatment or no clinical tasks; formal recognition and strict regulation by law, or absent recognition and regulation by the profession itself; regulated training with national examination or no formal training program; general or minor application of a quality system based on ISO norms.

The many details of the professional situation in the EU are complicated, and had to be abstracted for practical reasons. The differences between countries are illustrated by some examples. In France, the profession of medical biology (*biologie médicale*) is regulated by and reserved for medical doctors and pharmacists. The profession covers the fields of microbiology, parasitology and virology, biochemistry, hematology and immunology, IVF and genetics. In Portugal, only medical doctors and pharmacists are allowed to be laboratory directors. In the UK clinical chemistry is a monovalent specialty that covers biochemistry including endocrinology, and is performed by both medical doctors (*chemical pathologists*) and scientists (*clinical biochemists*). In Croatia, clinical chemistry includes biochemistry, endocrinology, hematology, immunology and molecular methods but excludes microbiology. At the moment there are only specialists of scientific background in Croatia, but a training program for physicians was started when this country entered the EU. The Netherlands is the only country without training for physicians to become medical laboratory specialists, where the training was stopped in 2001.

It is not so easy to fully document the characteristics in some countries and the differences between the practice of medical and scientific specialists. In Germany the polyvalent laboratory medicine has to be practiced by physicians as this includes microbiology and transfusion medicine with an important diagnostic and advisory task towards clinicians. Laboratory medicine in Slovak Republic is a general (polyvalent) medical discipline with a curriculum matching that of the UEMS, introduced in 2003 when hematology, microbiology and transfusion medicine were included in the curriculum for physicians. Scientists practice the monovalent discipline of clinical biochemistry. The curriculum of both disciplines overlap by 65%. Since the introduction, 10 physicians and 30 scientists have been trained according this new curriculum. In Spain a new law will come into effect this year. The monovalent specialties *bioquímica clínica* and the polyvalent specialty *análisis clínicos* will vanish and there will be only one kind of polyvalent specialists in laboratory medicine. This specialty training will accept students with training in medicine, pharmacy, biology and (bio)chemistry.

There are many efforts to harmonize the profession of laboratory medicine within Europe. One aspect of this process is the documentation of the similarities and differences between countries, as was done with our present study. Others in the laboratory profession have undertaken the same task [10, 11]. The EFLM has adopted the name of the specialty to be "*specialist in laboratory medicine*" [3]. This is expected to make the laboratory profession better recognizable. The EC4 has published an updated version of the guide to the EC4 register which gives the minimum standards of clinical chemistry education and training [6].

The UEMS Section of Laboratory Medicine/clinical biopathology has, however, worked on standards for training that describe the different specialties within the Section (clinical chemistry, hematology, immunology,

transfusion medicine, genetics and general/polyvalent laboratory medicine) [7]. Other medical specialties have worked successfully on harmonization within the EU [12]. The laboratory physicians are subject to the same UEMS charters and EC directives as other medical specialists, like the Charter on Training of Medical Specialists [13]; the Charter on Continuing Medical Education [14]; the Charter on Quality Assurance in Medical Practice [15]; the Charter on Visitation of Training Centres [16]. These rules and regulations might pose a special challenge in the harmonization between medical and scientific laboratory specialties.

Recent developments on EU level have opened new opportunities for harmonization. The EC directive on Recognition of Professional Qualifications has been revised and allows harmonization by "Common Training Frameworks" for recognition of professions within the EU when some conditions are met [1, 2]. One of these conditions is the recognition of a candidate profession within one third of the EU countries. European recognition of specialists in laboratory medicine with a scientific or pharmaceutical background might be within reach, starting with a defined profession and harmonized training in at least ten countries. Laboratory specialists of scientific background and of medical background are operating in the same professional domain, however, with other professional opportunities with respect to patient care. The respective training programs show considerable overlap or are in some countries even identical. For that reason this harmonization cannot be regarded as an independent process in the future.

Conclusions

The harmonization of the postgraduate training of both clinical chemists and of laboratory physicians has been a goal for many years, based on the concept of free movement of people within the EU. Much has been achieved within the respective European organizations in the development of curricula. A start has been made towards visitation of laboratories and specialist training across borders. There still exist major differences between the organization of the laboratory profession in the respective countries, which all have a long historical development with their own rationality. It will be an important challenge to harmonize the profession, and difficult choices will need to be made. Recent developments with respect to the EU directive on Recognition of Professional Qualifications call for new initiatives to harmonize laboratory medicine both across national borders, and across the borders of scientific and medical professions.

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