

The Practice of Clinical Chemistry in the European Union

Gerard T. Sanders^{1*}, Graham H. Beastall², Klaus P. Kohse³, Simone Zérah⁴, Rob Jansen⁵, Ursula Köller⁶, Vic Blaton⁷, Erik Lund⁸, Markku Parviainen⁹, Jo Charret¹⁰, Eberhard Gurr¹¹, Hara Nicholou¹², Desmond Kenny¹³, Mario Pazzagli¹⁴, Matthias Opp¹⁵, Hans Willems¹⁶, Maria do Carmo Martins¹⁷, José M. Queraltó¹⁸, Britta Landin¹⁹, Anna Yu²⁰ and Janet McMurray²¹

European Communities Confederation of Clinical Chemistry (EC4), EC4 Register Commission

¹ Department of Clinical Chemistry, Academic Medical Center (AMC), Amsterdam, The Netherlands

² Department of Clinical Biochemistry, Royal Infirmary, Glasgow, United Kingdom

³ Institut für Laboratoriumsdiagnose und Mikrobiologie, Klinikum Oldenburg, Oldenburg, Germany

⁴ Laboratoire d'analyses de biologie médicale, Bagnolet, Paris, France

⁵ Department of Clinical Chemistry, St Anna Hospital, Geldrop, the Netherlands

⁶ Institute for Medical and Chemical Laboratory Diagnostics, Hospital Lainz, Vienna, Austria

⁷ Department of Clinical Chemistry, AZ Sint Jan Hospitaal, Brugge, Belgium

⁸ Department of Clinical Chemistry, Vejle County Hospital, Vejle, Denmark

⁹ Kuopio Technology, Centre Teknia Ltd., Kuopio, Finland

¹⁰ SFBC et Ordre National des Pharmaciens Biologistes, Lyon, France

¹¹ Zentrallaboratorium, Zentralkrankenhaus Links der Weser, Bremen, Germany

¹² Hormone Laboratory, Department of Endocrinology, Evangelismos Hospital, Athens, Greece

¹³ Department of Clinical Biochemistry, Our Lady's Hospital for Sick Children, Crumlin, Dublin, Ireland

¹⁴ Clinical Biochemistry Unit, Department of Clinical Pathophysiology, Florence, Italy

¹⁵ Laboratoire National, Luxembourg, Luxembourg

¹⁶ CKCL, Academisch Ziekenhuis Sint Radboud, Nijmegen, The Netherlands

¹⁷ Instituto Nacional de Saúde Dr. Ricardo Jorge, Lisbon, Portugal

¹⁸ Servei de Bioquímica, Hospital de la Santa Creu i Sant Pau, Barcelona, Spain

¹⁹ Department of Clinical Chemistry, Huddinge University Hospital, Huddinge, Sweden

²⁰ Department of Clinical Chemistry, Danderyd Hospital, Stockholm, Sweden

²¹ Clinical Biochemistry Department, Hope Hospital, Salford, United Kingdom

level of clinical chemistry in the European Union. Closer contacts between the national societies for clinical chemistry have resulted in more comparable programs for postgraduate training of clinical chemists, closer similarity of contents and practice of the profession in the different countries, and the official registration of professionals. This article reviews some of the characteristics of professional organisation, practice, and regulation in the fifteen European Union countries. Many similarities appear. In half of the countries microbiology, blood-banking and transfusion medicine fall within the domain of clinical chemistry. The minimum number of years for training (university and postgraduate) is eight, but in practice this will extend to 10 or more years. Official regulation of the profession by law exists in a minority of countries. Continuing education and re-registration have not been officially instituted yet in any country, but these issues will be the next steps forward. In those countries that prepare themselves for entering the European Union, training and practice of clinical chemistry are moving towards the common standards of the European Communities Confederation of Clinical Chemistry. Clin Chem Lab Med 2002; 40(2):196–204

Key words: Postgraduate training; European Register; Education; Registration.

Abbreviations: EC4, European Communities Confederation of Clinical Chemistry; EU, European Union; FESCC, Forum of the European Societies of Clinical Chemistry; IFCC, International Federation of Clinical Chemistry and Laboratory Medicine; NCCRC, National Clinical Chemistry Registration Committee.

Introduction

Since its start, the European Communities Confederation of Clinical Chemistry (EC4) has been actively engaged in further improving the level of our profession in the European Union (1, 2). In Europe, EC4 is the Confederation of Clinical Chemistry societies within the European Union (EU). Via FESCC, comprising all European member societies of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), EC4 is linked to IFCC. The efforts of EC4 have brought a great deal of common regulation in clinical chemistry in the EU. One of the elements in this process is the institution of the EU Register for Clinical Chemists (3, 4). The basis of this is formed by the European syllabus for post-graduate training in clinical chemistry (5). All activities of creating a common platform for our profession have led to closer contacts between the national societies for clinical chemistry, resulting in more com-

The European Communities Confederation of Clinical Chemistry has been actively engaged in raising the

*E-mail of the corresponding author: g.t.sanders@amc.uva.nl

parable programmes for the vocational training of clinical chemists, closer similarity of contents and practice of the profession in the different countries, and the official registration of professionals. It is the goal of this article to give an overview of some of the characteristics of professional organisation, practice, and regulation in the fifteen EU countries.

In this process of regulation and co-operation, some aspects of professional practice have been dictated by the way in which the health care system has been organized in the respective EU member states. It has always been the policy of EC4 to respect these national regulations. Also, throughout this article the profession will be indicated as "clinical chemistry", but in many countries other names such as "clinical biology", "biologie clinique", "biochimia clinica", or "clinical biochemistry" are used (4).

Countries are listed in alphabetical order; practice, training, registration and number of clinical chemists are indicated.

1. Country: Austria

Clinical chemistry is practised by MDs, chemists, biologists, and pharmacists.

Official Register for MDs, kept by the Medical Chamber of Austria (State Health Board) delegated to the two scientific societies (ÖGKC and ÖGLM).

Training programme: University: 6 years; Vocational: 6 years (as part of Medical and Chemical Laboratory Diagnostics). Vocational training can take place in any recognised hospital laboratory (university hospitals and those general hospitals that are granted permission by the Government). Training programme for subjects within the domain of clinical chemistry matches the European syllabus. Final examination after vocational training will start in 2002. Re-registration is not being considered at the moment, but credit-points can be earned for continuing education.

NCCRC: National Registration Committee of the Austrian Society (ÖGKC).

Remarks: Only MDs can be head of a clinical laboratory; for clinical scientists there is no formal specialty training; they can be trained (clinical chemistry as part of the 6-year university education), but this does not lead to registration; they are not officially allowed to practise and they cannot be head of a clinical laboratory.

Number of clinical chemists: 450; MDs 62%, (bio)chemists 15%, pharmacists 12%, biologists and others 11%.

Clinical chemistry comprises clinical chemistry, haematology, blood-banking, immunology, microbiology.

National Society represented in EC4: Österreichische Gesellschaft für Klinische Chemie (ÖGKC).

2. Country: Belgium

Clinical Chemistry is practised by MDs, pharmacists, and (bio)chemists.

Official Register under the law of 20 July 1984 for all clinical biologists. This register is kept by the Ministry of Health.

Training programme: University: 5 years for pharmacists and chemists; 7 years for MDs; Vocational: minimum 5 years = 2 years the common training programme (*truncus communis*) + 3 years specialisation; it is essential after the common training programme (*truncus communis*) and the further 3 years training to obtain registration in clinical biology. Vocational training in university hospitals and hospitals is affiliated to the university; for pharmacists and chemists a programme is organised by the faculty. Training programme for subjects within clinical chemistry matches the European syllabus. There is final examination after vocational training for pharmacists and chemists, but not yet for MDs. A continuing education system exists which is organised by the scientific associations. Credit-points are obtained and in the future this system will be the basis for re-registration.

NCCRC: This is a state-regulated system, delegated to the Société Belge de Chimie Clinique/Belgische Vereniging voor Klinische Chemie.

Number of clinical chemists: 460 pharmaceutical background; 450 MDs.

Clinical biology (clinical chemistry) comprises clinical chemistry, haematology, blood-banking, immunology, microbiology.

National Society represented in EC4: Société Belge de Chimie Clinique/Belgische Vereniging voor Klinische Chemie

3. Country: Denmark

Clinical chemistry is practised by MDs, (bio)chemists.

There is an Official Register for MDs (chemistry + analytical haematology), kept by the Danish Health Council.

Register for scientists (chemistry and analytical haematology) is kept by the Danish Society of Clinical Biochemistry.

Training programme: University: MDs 6 years; MScs: university degree in chemistry, biochemistry, pharmacy or biology, at least 5 years of university study; Vocational: MDs 7.5 years; PhDs 5 years separate training programme after which registration in a register kept by the Danish Society of Clinical Biochemistry. Vocational training: for MDs 3 centres are designated, for MScs any recognised hospital laboratory (university or general) headed by an MD specialist in clinical biochemistry. Training programme for subjects within clinical biochemistry matches the European syllabus. Final examination after vocational training: no. No re-registration at this point.

NCCRC: Danish Society of Clinical Biochemistry, National Register Committee UU II.

Remarks: There is no formal specialty training for clinical scientists; no official registration.

Number of clinical chemists: about 120 clinical scientists.

Clinical chemistry comprises clinical chemistry, haematology, blood-banking.

National Society represented in EC4: Dansk Selskab for Klinisk Biokemi.

4. Country: Finland

Clinical chemistry is practised by MDs (25%) and clinical scientists (75%).

Registration: For MDs after vocational training, the Medical Faculty awards a certificate; for science-based clinical chemists, the Medical Faculty gives recommendation to the National Board of Training, which awards a certificate.

Registers: Central Medical Board registers clinical chemists (MDs) as medical professionals with a legal status; science-based clinical chemists (hospital chemists) are registered by the National Board of Medicolegal Affairs as professionals with a protected title (this equals a legal status).

Training programme: University: MDs 6 years; clinical scientists 4–5 years minimum (in practice 6 years); Vocational: MDs 5 years (subspecialisation + 2 years); science-based 5 years. Vocational training can take place in any recognised hospital laboratory (university and general; the latter for a limited time span only). The training programme for subjects within clinical chemistry matches the European syllabus. Final examination after vocational training is obligatory for MDs and scientists. Continuing medical education: not obligatory yet; in the future continuous education may be linked to accreditation.

NCCRC: A special committee has been created for both MDs and scientists by the Finnish Society of Clinical Chemistry.

Remarks: There are five faculties of medicine that teach clinical chemistry for MDs; there are two faculties of medicine that teach clinical chemistry for science-based clinical chemists.

Number of clinical chemists: science-based 221, of which 137 are officially registered; MDs 88.

Clinical chemistry comprises clinical chemistry, haematology, blood-banking, immunology.

National Society represented in EC4: Finnish Society of Clinical Chemistry (SKKY).

5. Country: France

Clinical chemistry is practised by MDs, pharmacists and a few veterinarians; regulated by law of 10 September 1990.

Official Register: Two registers exist, one for pharmacists and one for MDs. They are kept by the Orders

and Public Authorities, namely "Section G" of the Order of Pharmacists and the Order of MDs.

Training programme: University: 6–7 years; Vocational: 4 years. Vocational training takes place in university hospitals; it is obligatory to have been resident in a teaching hospital (Centre Hospitalier Universitaire; CHU). Training programme for subjects within clinical chemistry matches the European syllabus. Final examination after vocational training: during the training period there are five examinations in parasitology, biochemistry, haematology, bacteriology and virology, immunology. Thesis is recognised at the end of training period. Every professional is re-registered by the Conseil de l'Ordre on a yearly basis, as long as he/she is professionally active; there is no formal continuing education.

NCCRC: Consists of a representation of each of the two Conseils de l'Ordre (Medecins and Pharmacists), hospital laboratories, private laboratories, the President of the SFBC and a representative of the MDs.

Number of clinical chemists: MDs 2000, pharmacists 8000 (4000 clinical chemists work in private laboratories).

Clinical chemistry (*biologie clinique*) comprises clinical chemistry, haematology, blood-banking, immunology, microbiology (bacteriology, virology, parasitology).

National Society represented in EC4: Société Française de Biologie Clinique (SFBC).

6. Country: Germany

Clinical chemistry is practised by MDs and scientists.

Register: There is no official for clinical scientists. This Register is kept by the German Society of Clinical Chemistry (Commission for the Recognition as Clinical Chemist); Register is open to MDs and scientists. A separate Register exists which is open for MDs with a 5-year vocational training in laboratory medicine (including clinical chemistry); it is kept by the College of Physicians under delegation of the Government.

Training programme: University: 5 years (MD) and minimum of 4 years (scientists); Vocational: 5 years minimum for single degree; 3 years for MD+PhD. Vocational training can take place in any recognised hospital laboratory (university and general). Training programme for subjects within clinical chemistry matches the European syllabus. Final examination after vocational training is obligatory. No official re-registration system exists; plans are being developed for MDs, based on a credit-point system.

NCCRC: German Society of Clinical Chemistry.

Number of clinical chemists: 500 registered clinical chemists (250 MDs and 250 clinical scientists).

Clinical chemistry comprises clinical chemistry, haematology and immunology.

National Society represented in EC4: Deutsche Gesellschaft für Klinische Chemie (DGKC).

7. Country: Greece

Clinical chemistry is not an officially recognised specialty in Greece so far. As a consequence, there is no official register, training or examination for this specialty. Clinical chemistry, named medical biochemistry in Greece, is part of the MD speciality called biopathology (formerly microbiology).

In the public sector scientists (chemists, biochemists, biologists) form the great majority of the staff of the State Hospital laboratories, with only a few MDs.

In the private sector only MDs can run their own laboratory, since the specialty (biopathology) is within the medical domain; consequently MDs obtain the Government license to work for the private sector. Many scientists work in the big outpatient clinics, but not as heads of the laboratories.

Register: For MDs an official Register for Biopathologists is kept by the Government. For scientists an unofficial Register is kept by the Greek Society of Clinical Chemistry – Clinical Biochemistry. The requirements are 5 years of service in a state hospital laboratory or/and a PhD in clinical chemistry. This Register is also open to MDs specialised in biopathology, who work in a state hospital clinical chemistry laboratory. The qualifications are judged by the Executive Board of the Society.

Training programme: University: for scientists 4 years, for MDs 6 years; postgraduate studies: MScs 2 years, PhDs 3–5 years; Vocational: no vocational training in clinical chemistry itself exists for scientists, only “recognised experience” in state hospital laboratories. For MDs there is 1 year official training in clinical chemistry as part of the overall biopathology training. Training programme for subjects within clinical chemistry does not match the European syllabus. The Greek Society for Clinical Chemistry – Clinical Biochemistry has organised an unofficial training programme and continuous education with 1- or 2-day seminars covering most fields of clinical chemistry. No official examination is required.

Number of clinical chemists: 340.

Clinical chemistry comprises clinical chemistry, haematology, blood-banking, immunology and microbiology.

National Society represented in EC4: Greek Society of Clinical Chemistry.

8. Country: Ireland

Clinical chemistry is practised by clinical scientists and chemical pathologists (medically qualified clinical chemists).

Register: Register of Medical Specialists (Chemical Pathologists only). No register exists for scientists; new Government regulations for registration are under discussion.

Training programme: University: 1) BA or BSc in an appropriate science subject (usually biochemistry): 4 years; 2) medical degree: 6 years; Vocational: 1) with a science degree: 8 years post-basic-degree experience

and training, with at least 5 years of this in a laboratory recognised for training by the Royal College of Pathologists (UK), and attainment of PhD and/or MRCPATH (the MRCPATH requires a minimum of 5 years training approved by the Royal College of Pathologists (UK)); 2) with a medical degree: 6 years recognised experience. The regulations require (a) full registration in the Irish General Register of Medical Practitioners, and (b) possession of the MRCPATH or an equivalent qualification (*e.g.* Certificate of an American Board), and either (c) inclusion in the chemical pathology division of the Irish Register of Medical Specialists, or 6 years satisfactory postgraduate training and experience in the medical profession, including 5 years in chemical pathology. Possession of the MRCPATH requires a minimum of 5 years training approved by the Royal College of Pathologists (UK). Science graduates may not take the final examination until 8 years after their primary degree. Training programme for subjects within clinical chemistry matches the European syllabus. Final examination after vocational training: Membership of Royal College of Pathologists (examinations part I and II). Continuing medical education: continuing medical education programme is run by the Royal College of Physicians in Ireland (scientists and medical); this is on a trial basis and at the moment is not compulsory.

NCCRC: No register exists at the moment, but the national society has established an Advisory Committee for the EC4 Register to provide advice to the EC4 Register Commission and to Irish applicants for registration.

Number of clinical chemists: 90 science-based, of which 15 are estimated to qualify for a register at higher specialist level; 4 medical at higher specialist level.

Clinical chemistry comprises clinical chemistry (clinical biochemistry).

National Society represented in EC4: Association of Clinical Biochemists in Ireland.

9. Country: Italy

Clinical chemistry is practised by MDs and clinical scientists (biologists, chemists and pharmacists; CTF: a pharmaceutical technical degree at a university graduate level is presently under development).

Register: No official register exists (national evaluation, *i.e.* University degree equals registration).

Training programme: University: 5 years (scientists) or 6 years (MDs); Vocational 4 years; mainly “diagnostic” for MDs; mainly “technical-analytical” for others. Vocational training is carried out at university medical faculties in clinical laboratories. Training in clinical chemistry after MD degree or other university degrees is given as a degree of specialty only by the University Medical Schools. However, part of the experience and training is given also by some other accredited hospitals or laboratories. Training programme for subjects within clinical chemistry mostly matches the European syllabus. Presently, there is no final examination after vocational training. Continuing medical education:

credit-points can be obtained for continuing education; evaluation takes place every 5 years.

NCCRC: No law has been passed for one national register; the societies have to set up their own register.

Number of clinical chemists: MDs about 4000; clinical scientists about 4000. About 5000 laboratories: 35% public, 65% private. Most private laboratories are run by clinical scientists.

Clinical chemistry comprises clinical chemistry and basic haematology, immunology, microbiology, genetics and clinical molecular biology.

National Society represented in EC4: Società Italiana di Biochimica Clinica e Biologia Molecolare Clinica (SIBioC).

10. Country: Luxemburg

Clinical chemistry is practised by MDs, (bio)chemists, pharmacists.

No official register exists at the moment. Two laws (Loi du 16 juillet 1984 relative aux Laboratoires d'Analyses Médicales, and Règlement grand-ducal du 18 septembre 1998 déterminant les Disciplines d'un Laboratoire d'Analyse de Biologie Médicale et Règlementant la Formation Spécialisée des Responsables de Laboratoire) describe the conditions to be fulfilled prior to the authorisation to run a laboratory (Ministry of Health). The Ministry of Health judges whether the degree obtained is right. Private laboratories need a special license to practise in every separate specialty.

Training programme: about 10 years; University: in Luxemburg there are no universities, therefore all training takes place abroad (mainly in Belgium and France, but also in Germany and Austria); Vocational: outside the country (5 years specialty training is proposed). Vocational training according to the rules set in the foreign EU country where the training takes place; specialty training also takes place on the job. Training programme for subjects within clinical chemistry matches the European syllabus: not applicable. Presently, there is no final examination after vocational training and no re-registration.

NCCRC: Luxemburg Society of Clinical Chemistry (in cooperation with the Ministry of Health).

Remarks: There is no formal specialty training for clinical chemists and no register at present.

Number of clinical chemists: 6 MDs; all other specialists (about 50) have a background in pharmacy or chemistry.

Number of private and clinical laboratories: 30.

Clinical chemistry comprises clinical chemistry, haematology, blood-banking, immunology and microbiology.

National Society represented in EC4: Société Luxembourgeoise de Biologie Clinique. Technicians are also members of the Luxemburg Society of Clinical Chemistry.

11. Country: Netherlands

Clinical chemistry is practised by MDs and science-based clinical chemists: (bio)chemists, pharmacists, biologists and others with a relevant university degree.

Register: MDs are officially registered; for others a non-official register exists. These Registers are kept by: 1) for MDs by Specialists Registration Committee of the Royal Medical Association of the Netherlands (by delegation from Ministry of Health); 2) for science-based clinical chemists by the Registration Commission of the Netherlands Society of Clinical Chemistry.

Training programme: 8–10 years; University: 4–6 years; Vocational: 4 years for MDs and PhDs (in case of an MSc entering the profession, the training is extended to 6 years). Vocational training takes place in any recognised hospital laboratory (university and general). Training programme for subjects within clinical chemistry matches the European syllabus. Final examination after vocational training: annual examinations on specific subjects covering the complete domain of clinical chemistry. Continuing medical education: A country-wide system exists. Participation is voluntary, no effect on re-registration, although an experiment has started.

NCCRC: Registration Commission of the Netherlands Society of Clinical Chemistry

Number of clinical chemists: MDs 15; science-based: 300.

Clinical chemistry comprises clinical chemistry, haematology, blood-banking, immunology and molecular biology.

National Society represented in EC4: Nederlandse Vereniging voor Klinische Chemie (NVKC).

12. Country: Portugal

Clinical chemistry is practised by MDs and pharmacists (public and private sectors).

Registers: The Ministry of Health has transferred the right to keep Registers to the following associations: the Association of Pharmacists (*Ordem dos Farmacêuticos*) and the Medical Association (*Ordem dos Médicos*) for professionals working in the private sector. Clinical chemistry is a section of Clinical Analyses, which is the name of the specialty and of the Register. These Registers, applying only to MDs and pharmacists working in the private sector are not official (*i.e.* the Government never has ordered the associations to keep the Registers). The practice of clinical analyses for the private laboratories is regulated by the Ministry of Health in connection with the Medical and Pharmaceutical Associations through several regulations, the most recent one is that of April 2001 approving the Manual of Good Laboratory Practice (*Despachos*, numbers 8835, 8836, 8837, 8838).

Training programme: University: 6 years (MDs), 5.5 years (pharmacists); Vocational: 4 years. Vocational training takes place in any approved laboratory (university, hospital, public institute, private). Training pro-

programme for subjects within clinical chemistry matches the European syllabus. Final examination after vocational training is the responsibility of the Professional Associations of MDs and Pharmacists. Re-registration is under discussion and will be an issue in the near future; continuing education is not officially implemented, but in reality already exists.

NCCRC: Ordem dos Farmacêuticos/Ordem dos Médicos.

Number of clinical chemists: 1000 (400 MDs; 600 pharmacists).

Clinical chemistry comprises clinical chemistry, haematology, endocrinology, immunology and microbiology; blood-banking is a separate medical specialisation.

Remarks: The directorship of hospital laboratories is the prerogative of MDs; only MDs and pharmacists can run a private laboratory. Biochemists, biologists and other scientists can work in clinical laboratories either in the private or the public sector, though they cannot lead them. They can work in clinical laboratories with an individual contract or enter in a special career – *Careira de Técnicos Superiores de Saúde* – now with two branches: laboratory or genetics.

National Society represented in EC4: Sociedade Portuguesa para o Desenvolvimento da Bioquímica e Biologia Clínicas (SPDBBC).

13. Country: Spain

Clinical chemistry is practised by graduates in medicine, pharmacy, biological sciences (biologists) and chemists (as core clinical biochemistry specialists or general laboratory specialists, “analistas clínicos”).

Clinical biochemistry has been a recognised medical specialty since 1978, and a pharmaceutical specialty since 1982 (regulated by law), under supervision of the Ministries of Health and Education.

There is an official Register for professionals in the “Colegio”. Every professional should register his degree in the provincial “Colegio”: doctors, pharmacists, biologists and chemists. Registration of the specialist title is not compulsory except for private practice. The Ministry of Education keeps a register of diplomas that have been issued. Official regulations exist for physicians and pharmacist. Postgraduates in chemistry and biology are given a certificate which allows them to practice in equivalence with MDs and pharmacists, but no legal regulation exists.

Every province has its own registers; more than 108 registers exist; 4 “Colegios” per province at 50 provinces means a maximum number of 200 registers.

The National Commission for Clinical Biochemistry (medicine), the National Commission for Clinical Biochemistry (pharmacy) and the National Commission for Clinical Analyses both in medicine and pharmacy exist mainly as Advisory Boards for the Ministries of Health and Education in specialty and educational affairs.

Training programme: University: MD: 6 years; phar-

macists, chemists, biologists: 5 years; Vocational: 4 years (recognised by the National Joint Commission). Vocational training takes place in any recognised (accredited) hospital laboratory (university and general). Accreditation is granted by Ministries of Health and Education following the recommendations of the National Commission, supported by the Federation of Colegios of Medical and Pharmaceutical Specialties, a body formed by the chairmen of every specialty in the National Joint Commission. Training programme for subjects within clinical chemistry matches the European syllabus. Training: Laws regulate the training for medical and pharmaceutical specialists, under supervision of the National Joint Commissions, separate for medical and pharmaceutical registration; biologists and chemists follow the same training rules, not specified by law. Final examination after vocational training: not yet, annual evaluation by head of laboratory. Re-registration has not yet been implemented; there are initiatives for continuing education.

NCCRC: Sociedad Española de Bioquímica Clínica y Patología Molecular (SEQC).

Number of clinical chemists: public: monovalent (clinical biochemists): 400, polyvalent (clinical analysts): 1000; private: monovalent (clinical biochemists): 50, polyvalent (clinical analysts): 1500. Ratio pharmacists/MDs is approximately 3:1; biologists and chemists form less than 10% of the total.

Polyvalent clinical chemistry comprises clinical chemistry, haematology, blood-banking, immunology, microbiology; monovalent clinical chemistry: clinical chemistry and molecular biology.

National Society represented in EC4: Sociedad Española de Bioquímica Clínica y Patología Molecular (SEQC).

14. Country: Sweden

Clinical chemistry is practised by MDs and professionals from other disciplines.

MD clinical chemists are registered by the National Board of Health and Welfare, which is a governmental body.

Training programme: University: medicine 7.5 years; in science different educational pathways of varying length can be followed (minimum 5 years); Vocational: 5 years. Vocational training takes place in any recognised hospital laboratory (university and general), but it is strongly recommended that at least part of the time is spent in a university hospital laboratory. Training programme for subjects within clinical chemistry matches the European syllabus. Final examination after vocational training: voluntary final examinations for MDs under training have been performed yearly since 1990. The 2-day examination comprises a written part (1 day) and an oral session (1 day) before an examination board. Continuing medical education: The programme exists, but presently there are no formal rules for recertification.

NCCRC: Socialstyrelsen (<http://www.sos.se>).

Remarks: There is a formal specialty training and registration for MDs; no formal training and registration for clinical scientists presently exists.

Number of clinical chemists: 120 (MDs).

Clinical chemistry comprises clinical chemistry, laboratory haematology, blood-banking and immunology.

National Society represented in EC4: Svensk Förening för Klinisk Kemi (SFKK), which is one of the subgroups of the Swedish Society for Doctors of Medicine (Svenska Läkaresällskapet).

15. Country: United Kingdom

Clinical chemistry is practised by clinical scientists and chemical pathologists (medically qualified clinical chemists).

An official Register exists for medically qualified clinical chemists, which is kept by the General Medical Council (GMC). For scientists an official register is kept by the Council for Professions Supplementary to Medicine (CPSM).

Training programme: University: 3 (or 4) years to BSc + 2 years to MSc (scientists); 5 years (medical); Vocational: scientists: 3 years basic training (grade A) + 3 years higher training (Grade B) assessed by gaining membership of the Royal College of Pathologists (MRCPATH) by examination (minimum 8 years after first degree); medical: 1–2 years general medical training + 5 years specialist training assessed by gaining MRCPATH by examination. Vocational training takes place in any recognised hospital laboratory (university and general) approved by the Royal College of Pathologists. Training programme for subjects within clinical chemistry matches the European syllabus. Final examination after vocational training: examinations (part I and II) of the Royal College of Pathologists. Continuing medical education: Programme is run by the Royal College of Pathologists; credits are submitted annually

and evaluated every 5 years. This is presently not compulsory.

NCCRC: Subgroup from Clinical Scientists Board of Council for Professions Supplementary to Medicine (CPSM) on behalf of both scientists and medical practitioners.

Remarks: MRCPATH is qualification for head of a laboratory; for MDs Certificate of Completion of Specialist Training (CCST) equals MRCPATH + relevant experience. For medically qualified clinical chemists registration with the General Medical Council is compulsory; for scientists registration with the Council for Professions Supplementary to Medicine is compulsory.

Number of clinical chemists: 250 medical; 750 clinical scientists (fully qualified).

Clinical chemistry comprises: clinical biochemistry only.

National Society represented in EC4: Association of Clinical Biochemists (ACB).

Discussion

This paper deals with some aspects of the practice of clinical chemistry, and in the different EU countries many similarities appear. The contents of the discipline is summarised in Table 1. In half of the countries microbiology falls within the domain of clinical chemistry, and so do blood-banking and transfusion medicine. Of course, the data in this Table are not absolute. It may well be that in individual laboratories a different distribution of disciplines has evolved. For example, technological developments have enabled performing virology, parasitology and toxicology tests in clinical chemistry departments where microbiology and toxicology are not within the domain of clinical chemistry.

The minimum number of years for training (university and postgraduate) is eight. In practice, this will extend to 10 or more years (Table 2). Official regulation of

Table 1 Overview of the contents of clinical chemistry in the countries of the European Union.

Country	Clinical (biological) chemistry	Hematology	Immunology	Microbiology	Blood-banking
Austria	Yes	Yes	Yes	Yes	Yes
Belgium	Yes	Yes	Yes	Yes	Yes
Denmark	Yes	Yes	No	No	No
Finland	Yes	Yes	Yes	No	Yes
France	Yes	Yes	Yes	Yes	Yes
Germany	Yes	Yes	Yes	No	No
Greece	Yes	Yes	Yes	Yes	Yes
Ireland	Yes	No	No	No	No
Italy	Yes	Yes	Yes	Yes	No
Luxembourg	Yes	Yes	Yes	Yes	Yes
Netherlands	Yes	Yes	Yes	No	Yes
Portugal	Yes	Yes	Yes	Yes	No
Spain	Yes	Yes	Yes	Yes	Yes
Sweden	Yes	Yes	Yes	No	Yes
UK	Yes	No	No	No	No

Table 2 Overview of the vocational training in clinical chemistry in the countries of the European Union.

Country	Basic education		Duration of training (years)		Official register/legalisation	
	Medicine	Science	University	Postgraduate	Medicine	Science
Austria	Yes	B, C, P	6 and 5 ¹	6	Yes	No
Belgium	Yes	BC, P	7 and 5 ¹	5	Yes	Yes
Denmark	Yes	C, AH	8 and 5 ¹ to 6	5.5 and 5 ¹	Yes	No
Finland	Yes	Yes	6	6 and 5 ¹	Yes	Yes
France	Yes, V	P	6 to 7	4	Yes	Yes
Germany	Yes	Yes	6	5	No	No
Greece	Yes	Yes	6 and 4 ¹	5	Yes	No
Ireland	Yes	BC, C	4	8	No	No
Italy	Yes	B, C, P	5 to 6	4	Yes	No
Luxembourg	Yes	B, BC, P	Abroad	Abroad	Yes	Yes
Netherlands	Yes	Yes	6 and 5 ¹	4	Yes	No
Portugal	Yes	BC, C, P	6	4	Yes	No
Spain	Yes	B, C, P	6 and 5 ¹	4	Yes	Yes
Sweden	Yes	No	7.5	5	Yes	No
UK	Yes	BC, C	5 to 6	7 to 8	Yes	Yes

¹: MDs and scientists, respectively; B: biology, BC: biochemistry, C: chemistry, P: pharmacy, AH: analytical haematology, V: veterinary medicine

the profession by law exists in a minority of countries. When MDs, pharmacists or veterinary MDs are practising clinical chemistry, they are subject to the respective EU directives.

Continuing education, leading to re-registration for a certain number of years, is a subject of discussion in a number of countries but has not been officially instituted yet in any country. Such a system, in most countries, will be based on credit-points obtained for pre-defined professional education activities. It is to be expected that this issue will be one of the future developments.

The profession is practised in the different countries at the same level, regardless of the academic background of the professionals. Their professional tasks include in brief:

- Pre-analytical advice concerning the most appropriate laboratory investigation and the required frequency of testing in relation to a clinical problem;
- Responsibility for sampling of the patient including timing, selection of container, preservation and pre-analytical preparation of the sample;
- All aspects related to the analysis itself;
- Post-analytical consultation and clinical interpretation of data.

Some differences with the inventory for all FESCC countries observed by Rossier *et al.* (6) can be noted. They included activities related to accreditation in their overview; this article is dedicated to vocational training only. The years dedicated to vocational training are broadly similar in EU and non-EU countries. Also, the same range from monovalent to polyvalent practice of clinical chemistry can be noted in the non-EU countries as in the EU countries (Table 2). Enlarging the present European Union with countries listed in the survey of Rossier *et al.* (6) will be eased when the training programmes of the other FESCC countries will move to-

wards those implemented in the EU-countries at this time.

As a final remark it may be said that, although this article reflects the situation of clinical chemistry today, that cannot be considered to remain static for the years to come. It is expected that the main framework will remain more or less unchanged. Details could evolve with new developments and also with future attempts to form a common platform for clinical chemistry in the EU.

References

1. Sanders GTB, Kelly AM, Breuer J, Mocarelli P. The role of European Communities Confederation of Clinical Chemistry (EC4) in the harmonisation of clinical chemistry in the European Union [letter]. *Eur J Clin Chem Clin Biochem* 1995; 33:947–8.
2. Sanders GT, Jansen RT, Beastall G, Gurr E, Kenny D, Kohse KP, Zerah S. Recent activities of EC4 in the harmonization of clinical chemistry in the European Union. *Clin Chem Lab Med* 1999; 37:477–80.
3. Sanders GT, Kelly AM, Breuer J, Kohse KP, Mocarelli P, Sachs C. The European Register for clinical chemists. *Eur J Clin Chem Clin Biochem* 1997; 35:795–6.
4. Sanders GT, Kelly AM, Breuer J, Kohse KP, Mocarelli P, Sachs C. European Communities Confederation of Clinical Chemistry Guide to the EC4 Register: European clinical chemist. *Eur J Clin Chem Clin Biochem* 1997; 35:797–803.
5. Bousquet B, Brombacher PJ, Zerah S, Beastall GH, Blaton V, Charret J, *et al.* EC4 European syllabus for post-graduate training in clinical chemistry. Version 2 – 1999. European Communities Confederation of Clinical Chemistry, EC4 Register Commission. *Clin Chem Lab Med.* 1999; 37: 1119–27.
6. Rossier M, Blaton V, Franzini C, Queralto JM, Palicka V. FESCC survey on accreditation and post-graduate training

in clinical chemistry in European countries. Federation of European Societies of Clinical Chemistry. *Clin Chem Lab Med* 2000; 38:371–6.

Received 3 January 2002, accepted 8 January 2002

Corresponding author: Prof. G.T. Sanders, Academic Medical Center, Department of Clinical Chemistry B1-243, Meibergdreef 9, 1105 AZ Amsterdam, The Netherlands
Phone: +31 20 5662925, Fax: +31 20 6091222
E-mail: g.t.sanders@amc.uva.nl