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Registratie

Naar een Europees Register voor Klinisch Chemici

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De hierna volgende twee artikelen handelen over het opzetten van een Europees Register voor Klinisch Chemici. Het instellen van een dergelijk register is één van de activiteiten van de European Communities Confederation of Clinical Chemistry, EC 4.
Voornaamste doel van het Europese Register is de harmonisatie van de klinische chemie in Europa, maar ook zal het een belangrijke rol spelen in het versterken van de positie van individuele klinisch chemici en van ons vakgebied in de verschillende landen. Bovendien zal het de mobiliteit van beroepsbeoefenaren verhogen (1). Het register staat open voor alle erkende klinisch chemici in de Europese Unie (EU). Eind maart 1997 werd in Amsterdam door 14 van de 15 (uitzondering: Zweden) met de IFCC verbonden klinisch-chemische verenigingen in de EU de handleiding (2) voor een Europees Register geaccordeerd.
De komende maanden zullen worden gebruikt om het Register verder vorm te geven en om de noodzakelijke administratieve maatregelen te nemen om het Register daadwerkelijk van start te kunnen laten gaan. Tot zolang zullen de Nederlandse klinisch chemici nog moeten wachten alvorens ze zich tot Europees Klinisch Chemicus kunnen laten registreren.
Om grote bekendheid aan het in te stellen register te geven, is op de vergadering in Amsterdam eveneens afgesproken om de beide volgende publicaties zo veel als mogelijk te publiceren in de tijdschriften van de nationale verenigingen. Ook heeft publicatie plaats gevonden in het European Journal of Clinical Chemistry and Clinical Biochemistry (2,3).

Voorzitter EC4, voorzitter Working Group on Registration

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European Communities Confederation of Clinical Chemistry
European Register for Clinical Chemists

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To ensure freedom of movement of clinical chemists in the European Union common standards of education, training, experience and compliance with continuing professional developments have to be ensured. Therefore, the European Communities Confederation of Clinical Chemistry (EC4) is on the verge of implementing the European Register for clinical chemists and has composed a guide to it. This document describes the conditions to enter specialty training, the minimum standards for registration (university education and postgraduate vocational training with a minimum total of eight years), the competencies of those having obtained registration and the operation of the register. Registration guarantees professional and managerial competencies; the title obtained is "European Clinical Chemist". EC4 recognises the existing national registers as far as they are based on the minimal requirements as indicated. An EC4 Register Commission (EC4RC) will maintain and control the European Register, supported by National Clinical Chemistry Registration Committees (NCCRC). An NCCRC controls the quality of the education in each country and assesses candidates. An individual (EU citizen) applies on a

private basis for the European Register to EC4RC and, where applicable, accompanied by a statement from the NCCRC of the country of registration, stating that the applicant has the necessary qualifications. For EU citizens trained outside the EU the final decision is with EC4RC. Non-EU citizens trained in an EU country may apply for registration, supported by the NCCRC that granted national registration; non-EU citizens not trained in an EU country are not eligible for registration. Renewal of registration is once every five years.

Key words: European Register; harmonisation; professional training

Introduction to the document

The Treaty of Rome allowed freedom of movement within the European Union (EU) but in practice did not ensure employment as national diplomas were not recognised throughout the EU. In health care the public must be safeguarded by ensuring that practitioners are competent to practice. However employers and job-seekers have difficulties in proving competence if the applicant has been trained in another Member State.

The EU has attempted to overcome such difficulties by:

Sectoral Directives (issued between 1975-85). The minimum standards of education, training and experience are agreed at EU level. National diplomas which meet the criteria are agreed and published. They are automatically and mutually recognised, e.g. for medical doctors, general nurses, midwives, pharmacists, dentists, veterinary surgeons and architects.

General Directives (89/48/EEC, 92/51). Member States retain the right to regulate a profession and to determine the level of education, training and experience required to practice. National diplomas are not automatically recognised throughout the EU and a Member State may require a period of adaptation or demonstration of aptitude before recognising the competence of a professional from another EU Country e.g. physiotherapists, occupational therapists.

European Register. A profession at EU level agrees common standards of competence and national diplomas which meet these criteria. Registration is voluntary e.g. engineers (EUR.ING), chemists (EUR.CHEM.).

Clinical chemists have always recognised the benefits of automatic mutual recognition of national diplomas which meet agreed standards and applied for recognition of the profession by a sectoral directive in 1978 and 1990. There was however no political support as the Commission's efforts were concentrated on the larger professions. The General Directive did not benefit the profession at EU level as regulation of the profession depends on each Member State. The European Communities Confederation of Clinical Chemistry (EC4) therefore agreed to progress recognition of the profession by establishing a register.

The European Register for Clinical Chemists ensures common standards of education, training, experience and compliance with continuing professional development of all registrants. The standards have been agreed by the national societies of clinical chemistry.

Four important benefits result from the register:

- public health is safeguarded
- a registrant is automatically recognised as competent to practice within the EU
- high standards of education and training prevail throughout the EU
- the profile of clinical chemistry is raised within the EU.

For the individual clinical chemist registration as a European Clinical Chemist means:

- that he or she can prove to be a qualified clinical chemist since a guarantee for professional qualifications is given
- facilitation of free movement within the European Union
- support for recognition in those member states where under local law no protection of the profession exists.

Final Version

European Communities Confederation of Clinical Chemistry

Guide to the EC4 Register

European Clinical Chemist

Final version approved at the EC4 Register launching meeting in Amsterdam, March 8th 1997

Contents

5.0 Minimum Standards
5.1 Minimum standards to enter specialty training
5.2 Minimum standards for registration as a European Clinical Chemist
5.3 Evolution of Clinical Chemistry

6.0 Title

7.0 Competencies

8.0 National registers
8.1 Transitional situation

Operation of the Register

9.0 EC4 bodies
9.1 The EC4 Register Commission, EC4RC
9.2 The National Clinical Chemistry Register Committees, NCCRCs
9.3 The EC4 Committee of Appeal, EC4CA
9.4 Custody of the European Register

Procedures

10.0 Application
10.1 Validation of applications
10.1.1 EU citizens trained within the EU
10.1.2 EU citizens trained outside the EU
10.1.3 Non-EU citizens
10.2 Registration as a European Clinical Chemist
10.3 Certificates
10.4 Renewal of registration
10.5 Finances

Points of Contention

EC4 Code of Conduct

Introduction

1.0 *Clinical Chemistry*

According to the definition of the International Federation of Clinical Chemistry (IFCC), the name Clinical Chemistry will be used throughout this document. The specialty is defined as follows:
"Clinical Chemistry is 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 relevant to the cause of disease, the maintenance of health and the conversion of these data into specific and general patient and disease related information at the laboratory clinician interface. The discipline is committed to deepening understanding of health and disease through fundamental and applied research."

In addition it is stated that:
"Clinical Chemistry is the largest subdiscipline of Laboratory Medicine which is a multidisciplinary medical and scientific specialty with several interacting subdiciplines such as haematology, immunology, clinical biochemistry, and others. Through these activities clinical chemists influence the practice of medicine for the benefit of the public.
In many countries, the practice of clinical chemistry includes traditional clinical biochemistry as well as some components of microbiology, haematology, molecular biology and immunology.
Clinical Chemists are responsible for comprehensive laboratory services including, for example, management, quality assurance and informatics. They frequently conduct research in laboratory medicine. For these reasons their professional education needs to include basic scientific, analytical, clinical and management training combined with informatics."
Where "analysis" is written, the complete analytical process, including pre- and post-analytical phases, is understood.
In different Member States of the European Union (EU) the designation for Clinical Chemistry appears either by specialty denomination of Clinical Chemistry or associated with or included in other specialties under a broader denomination.
The designations for the specialty of Clinical Chemistry as used in the Member States of the EU are:

- clinical biology:

Belgium	biologie clinique/klinische biologie
France	biologie clinique
Italy	biochimica clinica patologia clinica
Luxembourg	biologie clinique/ biochemie

- clinical biochemistry:

Denmark	klinisk biokemi
Finland	kliinine (bio)kemia
Ireland	clinical biochemistry
Spain	bioquímica clínica
United Kingdom	clinical biochemistry / clinical chemistry / chemical pathology

- clinical chemistry:

Austria	Klinische Chemie
Germany	Klinische Chemie
Greece	klinikè chimeia
Netherlands	klinische chemie
Portugal	química clínica
Sweden	klinisk kemi

2.0 *EC4*

The European Communities Confederation of Clinical Chemistry (abbreviated as EC4) is the organisation linking all clinical chemistry associations within the different member states of the European Union (EU), recognised by the International Federation of Clinical Chemistry (IFCC) for that member state within the EU. It was founded in 1973 and its constitution formalised in 1993.

Moreover, close links exist with the Forum of European Societies of Clinical Chemistry (FESCC), which is the European organisation of clinical chemistry associations, recognised by the IFCC within the whole of Europe, as it is defined by the World Health Organisation.

2.1 *Objectives*

The objects for which EC4 was established are:

a) to promote the advancement of Clinical Chemistry within the European Union, and to do all such things as may in the opinion of the Board of EC4 spread or increase the knowledge and standing of Clinical Chemistry within the EU, co-operating thereby in conjunction with FESCC and IFCC;
b) to advise the European Union on Clinical Chemistry matters;
c) to co-operate with standardisation bodies in all matters relating to Clinical Chemistry;
d) to promote the regulation of the profession of Clinical Chemistry in the EU by maintaining a Register and by furthering the establishment of a Directive describing the practitioners of the discipline and the standards of education, training and experience required to achieve "Registered Clinical Chemist" status;
e) to promote the recognition of the European Clinical Chemist title and to protect it;
f) to foster high standards of professional education and practice by organising and auditing through the National Associations of Member States training programmes for practitioners of the profession and programmes of continuing education for practitioners of the profession, and by regularly reviewing them;
g) to co-operate with any examining body in Medicine or a basic science subject in promoting suitable qualifying examinations for members of the profession of Clinical Chemistry;
h) to promote accreditation of laboratories where clinical chemistry is practised by the formulation of standards which encompass all aspects of quality and to recognise a body within the Member State to ensure that such standards are met;
i) to co-ordinate the examination and evaluation of scientific equipment and reagents for use in Clinical Chemistry laboratories;
j) to advise on suitable design and size of laboratories.

In pursuit of these aims EC4 maintains a Register to which individuals may be admitted provided they meet the specified minimum requirements.

The EC4 Register

3.0 *Premise*

In each Member State laboratory medicine is organised within its own national health care system. EC4 respects these different structures and has created a Register based on a Syllabus for post-graduate training in order to:

a) guarantee that the minimal requirements for the education and training of the individual clinical chemist have been fulfilled for the benefit of health care in general, the individual patient, and the employer;
b) facilitate the comparability of professional training of clinical chemists inside the EU and to establish a framework of mutual recognition of qualifications in order to provide clinical chemists who wish to practise outside their country with a guarantee of ability;
c) to encourage a continuous updating of the quality of Clinical Chemistry and its practitioners by setting, monitoring and reviewing standards for the definition and practice of Clinical Chemistry in the EU;
d) to provide a source of information about the different systems of education and training in the Member States.

4.0 *Professional training*

EC4 has judged the respective values of the educational and professional systems in Europe and composed a Syllabus comprising all subjects necessary to achieve a high level of professional competence.

This European Syllabus for post-graduate training in Clinical Chemistry (latest version: November 1991, revision in preparation) describes the minimal scientific content of professional knowledge and training, appreciating the responsibility of each Member State to organise laboratory medicine within its own national health care system. Thus, although significant differences exist in the practice of Clinical Chemistry throughout the EU, a great number of core elements can be discerned. These are considered to be the minimum scientific requirements for those who want to be registered as a specialist. The attainment of these competencies is the threshold which opens the right to registration. Since the professional activities also imply in most cases managerial responsibilities, it is important that the subject of laboratory organisation and management is included in this training period.

The specialist who is registered on the basis of the above standards not only fulfils the professional objectives of EC4 but is also eligible to be the head of a laboratory, one of the conditions necessary for its accreditation (Section 2.1 h).

5.0 *Minimum standards*
The education of Clinical Chemists in the EU can be said to be based in all countries on an identical scheme. It comprises a university education, followed by a specialisation in Clinical Chemistry. The standards stipulated below are the minimum required for admission to the register.

5.1 *Minimum standards to enter specialty training*
The minimum standard to enter specialty training is a university degree in medicine, chemistry, biochemistry, pharmacy or another relevant basic science subject which allows entry to the post-university specialty training.

5.2 *Minimum standards for registration as a European Clinical Chemist*
The minimum standard for registration as a European Clinical Chemist is a total of eight years of university and postgraduate study. A minimum of four years of postgraduate study after gaining a university degree must be spent on specialist training in a laboratory in a medical environment approved and supervised by the national body functioning for that purpose within the health care system of the Member State.

5.3 *Evolution of Clinical Chemistry*
In a number of countries within the EU there is an increasing trend for Clinical Chemistry to encompass a number of disciplines. As a result the professional training can be multidisciplinary (i.e. Clinical Chemistry and for example Haematology, Immunology, etc) as well as in a single discipline (i.e. Haematology). Training could be multidisciplinary initially, followed by specialisation. In all cases the conditions as specified in Section 5.2 will be valid.

6.0 *Title*
Registration as "European Clinical Chemist" gives the right to be called European Clinical Chemist in the language of the National Member State and to use the professional title European Clinical Chemist (invariable in all member countries) with the national title, if lawful.

7.0 *Competencies*
Clinical chemists having obtained registration in the EC4 register for Clinical Chemistry should be aware of their professional responsibilities and should have achieved competence in the following:

a) understanding of the registrants' responsibility in the practice of his profession to the well-being and personal safety of his colleagues, co-workers and patients, to the community, and to the environment;
b) thorough knowledge of all aspects of clinical laboratory sciences relevant to the discipline practised as specified in the Syllabus (Section 4.0);
c) ability to obtain, to explore, and to employ knowledge and methods of investigation in the interest of health care and mankind;
d) broad knowledge of and insight into biochemical processes in human health and disease on a general and patient-specific level;
e) ability to work in a multidisciplinary environment and function as a consultant to his clinical colleagues and liaise with them in the interpretation of laboratory results;
f) ability to safeguard and protect the public against misuse of medical laboratory investigations;
g) knowledge of the principles of management leading to adequate direction, supervision and organisation of a laboratory department in a hospital or in any other health care environment resulting in the provision of competent service as laid down in a laboratory quality manual, based on good laboratory practice;
h) ability to assess conflicting and multivarious technical, financial and human considerations (e.g. care, quality, safety, cost, and time scale) both in the short and long terms and to find the optimal solution in relation to patient care;
i) adequate ability to apply current techniques in human resources management;
j) ability to communicate orally and in writing, including the production of clear, cogent reports and publications in refereed international scientific journals;
k) knowledge of the use of technology and analytical techniques relevant to the field of specialisation, an active appreciation of developments and an attitude of innovation and creativity in their implementation in the profession of clinical chemistry;
l) appreciation of developments both in science and technology and also in the understanding of disease in order to ensure the appropriate use of laboratory investigations and to optimise the advice provided on those investigations.

8.0 *National registers*
EC4 acknowledges the national registers as they function in the Member Countries and provided that they are in accordance with the minimum requirements and based on curricula making it possible for candidates to develop towards professional competence as described

in Section 4. In those Member States in the EU where Clinical Chemistry training is not (yet) organised according to the pre-defined requirements, the EC4 Board, the EC4RC (Section 9.1) and the National Registration Commission (Section 9.2) need to ensure that that standards required for each national register meet the minimum standards required for the EC4 Register.
The extra duration of the education in EC4 terms should be specified.

8.1 *Transitional situation*
EC4 realises that at the introduction of the Register described in this document, a transitional period will be necessary before all conditions can be fulfilled, before an individual may be registered.

Operation of the Register

9.0 *EC4 bodies*
The EC4 Board via its EC4 Register Commission (EC4RC, Section 9.1) is responsible for the Register and for modification of the standards in the light of changing technology or other developments. Standards are accordingly reviewed at regular intervals of not more than 5 years.
The European Register is maintained by the EC4RC, (Section 9.1) and is administered by the EC4 Secretariat General which keeps records of the registrations. Whenever possible the EC4RC will in its decisions seek advise of the National Clinical Chemistry Register Committees, NCCRCs (Section 9.2).

9.1 *The EC4 Register Commission, EC4RC*
The Register Commission is composed of one delegate from each Member State, preferably members of the NCCRC, and one member of the Board of EC4 who also chairs the meetings. National delegates would be members of the national society recognised by IFCC but they need not be officers of that society.
By the 1st of March of each year the EC4RC circulates to its members a list of all applicants for the European Clinical Chemist Title made during the previous calendar year.

9.2 *The National Clinical Chemistry Register Committees, NCCRCs*
The National Clinical Chemistry Register Committees, NCCRCs are national bodies composed of representatives from the national clinical chemistry associations and the Government, or any other body recognised for the purpose in that Member State. It is the task of these Committees to keep EC4RC well informed on the national education structure. The NCCRC assesses the suitability of candidates to hold the title of Registered Clinical Chemist of that Member State. Registrants in their National Register may then apply to EC4RC to be recognised as European Clinical Chemist.
In January of each year, the EC4 Secretariat General communicates to NCCRCs any agreed changes to the Register of European Clinical Chemists.

9.3 *The EC4 Committee of Appeal, EC4CA*
The EC4 Committee of Appeal, EC4CA, is a European body composed of independent experts from representative Member States. EC4CA acts on behalf of the EC4 Board in adjudicating on cases of applicants who appeal against a decision of the EC4 Board not to grant registration. EC4CA also advises the Board and EC4RC on equivalence when applicants have not followed standard education or training programmes.

9.4 *Custody of the European Register*
The European register is kept by the EC4RC. As stated under 9.2 in January of each year, the EC4 Secretariat General communicates to NCCRCs any agreed changes to the Register of European Clinical Chemists.

Procedures

10.0 *Application*
Application is open only to individuals who have the required qualifications, i.e. they must be trained and/or registered in an EU-country.

10.1 *Validation of applications*

10.1.1 EU citizens trained within the EU
As a general rule an EU citizen registered in an EU country is automatically eligible for EU registration by the EC4RC. It is the responsibility of the NCCRC of the country of registration to check the validity of his university education (as specified in 5.1) and professional training. Consequently, the minimum EC4 requirement has then been fulfilled (Sections 5.2 and 5.3).
An EU citizen who is not registered in an EU country, but was trained within the EU can apply for an EU registration to the EC4RC. It is the responsibility of the EC4RC to check the validity of his university education and professional training (see previous paragraph).
All applications must be made directly to EC4RC, and where applicable, accompanied by a statement from the NCCRC of the country of registration supporting the applicant and stating that the applicant has the necessary qualifications for registration as a European Clinical Chemist.
If the education and training are assessed as adequate it would be assumed that the applicant has achieved competence as defined in Section 7.0.

10.1.2 EU citizens trained outside the EU

EU citizens trained outside the EU and registered in an EU country can be considered for EU registration only if they have undergone an university education and professional training which meets the EC4 criteria. It is for the NCCRC of the country of registration to provide the EC4RC with the evidence to support the candidate. The final decision is with the EC4RC. The EC4RC does not give general decisions on the equivalence of diplomas or degrees accepted in EU member states.

10.1.3 Non-EU citizens

Non-EU citizens may be eligible for registration only if education and/or training of the applicant has taken place in an EU country according to the predefined conditions. The NCCRC of the country of training (and, when different, of country of registration) must support the application.

Non-EU citizens not trained in an EU country are not eligible for registration.

10.2 *Registration as a European Clinical Chemist*

The EC4RC decides on the basis of Sections 10.0 and 10.1. the eligibility of the candidate for registration. Successful candidates will be included in the Register centrally maintained by the Secretariat General.

Persons registered as European Clinical Chemists must abide by the EC4 Code of Conduct.

Any application not approved will be returned to the NCCRC and reasons for failure will be given.

In cases where the decision of the EC4RC is contested the EC4 Committee of Appeal may be engaged.

10.3 *Certificates*

Registration as a European Clinical Chemist is attested by a certificate prepared by the Secretariat General and signed by the President and one Board Member of EC4.

10.4 *Renewal of registration*

Continuing Registration as a European Clinical Chemist being dependent on the registrant remaining in practice and observing the EC4 Code of Conduct.

Registration should be renewed every five years through the relevant NCCRC.

10.5 *Finances*

EC4 and each national Clinical Chemistry association bear the costs of the administrative work involved in operating the Register and are entitled to recover this cost by charging a life spanning fee to the applicants.

Points of Contention

All cases of doubt or difficulty, relating to decision on individual applications, are referred to the EC4 Committee of Appeal (see 9.3) for decision. An individual may subsequently appeal in writing against this decision to the EC4 Board, whose decision is final and without appeal.

EC4 Code of Conduct

The EC4, considering

that one of the primary goals of EC4 is to stimulate the development of the profession of clinical chemist and to maintain his professional activities at a very high level

that EC4 has set up a European registration system, in which clinical chemists of all countries affiliated to the EC4 can be registered

that one of the conditions in order to get registered is that the clinical chemist involved undertakes to comply with this Code of Conduct

that this Code of Conduct is additional to and does not replace any Code of Conduct to which the registrant might be subject in his own country

has adopted the following Code of Conduct:

1. The clinical chemist shall put his knowledge and ability concerning laboratory diagnostics (among which the indication for analyses, the reliability of the results, the interpretation and scientific research) at the service of diagnosis, therapy and prevention of human and animal diseases.
2. In order to pursue an optimal fulfilment of his tasks and in accordance with what is regarded as a good practice in his profession and having regard to the laws of the country in which he is working, the clinical chemist shall
   a) maintain his competence at the highest level of quality by following all relevant (scientific and practical) developments concerning health care in general and clinical chemistry in particular, by participating in relevant training courses and by practising his profession on a regular basis;
   b) accept assignments only within the area of his competence; beyond this limit, he will seek the collaboration of appropriate experts.
3. The professional integrity and intellectual honesty of the clinical chemist shall be the guarantees of his impartiality of analysis, judgement and consequent decision.

4. The clinical chemist shall at any time avoid deceit in professional and scientific respect, such as fraud, plagiarism, concealment, improper omission of information, and expressing incorrect or misleading opinions.
5. Without prejudice to legislation on privacy applicable in the country where he is working, the clinical chemist will consider himself bound to respect the confidentiality of information obtained by him in his professional work. The clinical chemist will be on his guard against misuse of such information.
6. The clinical chemist will serve the individual patient to the best of his ability and provide the general public with clear information, only in his field of competence, to enable a proper understanding of health care matters of public interest.
7. The clinical chemist will display his commitment to the Clinical Chemistry profession by taking part in the activities of its associations, notably those which promote the profession and contribute to continuing training of their members.
8. As head and/or member of the team operating in the Clinical Chemistry laboratory, the clinical chemist will, given the specific circumstance of the situation concerned:
   a) obtain a clear definition of the services required of him and/or his team;
   b) see to it that all activities in the laboratory will be organised and executed as accurately and quickly as possible;
   c) take care of the safety and well-being of his colleagues and be conscious of nature and environment;
   d) behave himself honestly and respectfully towards the personal rights of his superiors, colleagues and subordinates by taking due account of their requirements and aspirations, provided they conform to the laws and ethics of their professions;
   e) strive for a high level of technical achievement which will also contribute to and promote a healthy and agreeable environment for his colleagues.
9. The clinical chemist will not accept any obligation that brings him in conflict with his professional independence. In particular he undertakes:
   a) not to solicit for, or accept, gifts, pecuniary advantages or benefits from the medical product or diagnostic industry, unless they are inexpensive and relevant to the practice of the clinical chemist;
   b) not to solicit for, or accept, hospitality at sales promotions, symposia or congresses and the like unless this hospitality is reasonable in level and secondary to the main purpose of the meeting and does not extend to persons other than health professionals;
   c) not to accept financial support from the industry, directly or indirectly, other than for events for purely professional and scientific purposes; such gifts must always be reasonable in level and remain subordinate to the main scientific object of the event and it must not be extended to other than health professionals.

NB. In this text “he” and “his” are taken respectively for “he/she” and “his/her”.