

## EC4: PRESENT AND FUTURE ACTIVITIES

Rob Jansen, EC4 President

Clinical Laboratory, St. Anna Hospital Geldrop, 5660 AB Geldrop, The Netherlands

*Summary:* EC4 is the organisation for clinical chemistry and laboratory medicine in the European Union. The main goals of EC4 are the recognition of professional qualifications, the influencing of ISO and CEN documents relevant for the profession, monitoring EU directives relevant for the profession, reaching equivalence of standards in accreditation in Europe for medical laboratories, defining guidelines on the laboratory investigation of disease, harmonisation of laboratory data via calibration. The European register of specialists in clinical chemistry and laboratory medicine is maintained by the EC4 Registration Commission. A number of working groups are active in reaching the goals set. In this article present and future activities are described.

*Key words:* Europe, professional qualifications, register, quality, accreditation, calibration, guidelines

### Introduction

The freedom of movement of people and goods within the European Union (EU) has a large impact for the member states. Particularly within health care it is important to demonstrate, or if necessary ensure, an adequate level of the quality of profession and practice, so that citizens know that health care is offered in their country at a level comparable to other countries. The importance of recognition also applies to laboratory medicine. This was envisaged by the National Societies of Clinical Chemistry in EU countries related to the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). The common political reality led to the institution of the European Communities Confederation of Clinical Chemistry (EC4) on 27th of April 1993. On September 14<sup>th</sup> 2002, the name was changed in conformity with that of IFCC and the Federation of European Societies of Clinical Chemistry and Laboratory Medicine (FESCC) to the European Communities Confederation of Clinical Chemistry and Laboratory Medicine (EC4). EC4

is the organization of societies for clinical chemistry and laboratory medicine in the EU and the Executive Board consists of representatives from the societies. The EC4 member societies are members of the IFCC as well of its broad European regional branch (FESCC).

### Strategy

In European health care, patients are treated in a health care »chain«. In this chain, patients move quickly from primary health institutes to secondary and tertiary institutes, and *vice versa*. This situation involves many health care workers and may include several different laboratories. Diagnosis and therapy are now central to health care and medical laboratories play an essential role in this. The broad spectrum of medical laboratory investigations makes the consultant role of the medical laboratory specialist ever more important. The quality of both professionals and laboratories, as well as continuity of laboratory data within and between laboratories is of the utmost importance.

Address for correspondence:

Dr. Rob TP Jansen  
Clinical Laboratory  
St. Anna Hospital Geldrop  
Post box 90  
5660 AB Geldrop  
The Netherlands

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EC4 is active in giving support to attain such quality and to ensure that laboratory medicine is practised at an adequate level throughout Europe (1).

In most countries this is already the case and EC4 plays a central role in co-ordinating mutual recognition on the basis of existing equivalence of standards. The Co-ordination of Automatic Recognition of Equivalence of standards (CARE) is important at three levels, CARE for the profession, CARE for quality of laboratories and CARE for laboratory data. Together, these result in proper standards of patient care.

### Goals of EC4

The goals of EC4 include co-operation and harmonisation in the field of laboratory medicine. The efforts are focussed on several aspects:

- Co-operation for the advancement of clinical chemistry and laboratory medicine as a science, in its fundamental aspects as well as in its application, within the European Union in particular and Europe in general.
- Co-operation to reach recognition of professional qualifications of the profession on a European level, in compliance with the principles of free movement of professionals within the EU.
- Co-operation and recognition of equivalence of standards in the field of training of specialists in clinical chemistry and laboratory medicine, irrespective of their varying academic background.
- Co-operation and recognition of equivalence of standards of accreditation and quality systems of medical laboratories.
- Co-operation to introduce a common professional view in ISO and CEN deliberations.
- Co-operation in defining guidelines on a European level for the performance of the profession and the laboratory management of disease.
- Co-operation in evaluating effects of EU directives on professional matters.
- Co-operation in evaluating effects of EU directives related to laboratories and laboratory data.
- Communicating with and informing the public on the significance of their laboratory data.

To reach the goals five main issues are elaborated.

- Profession Regulation
- Performance of the profession
- Performance of laboratories
- Liaison with European and other bodies
- Promotion of EC4 activities

### Profession Regulation (CARE for the profession)

#### *EC4 Register*

*Background.* The installation of the EC4 Register of European Specialists in Clinical Chemistry and Laboratory Medicine is a major step forward to the attainment of the first level, Recognition of Equivalence of Standards of the profession. Individual medical laboratory specialists should and do apply for registration. In most EU countries National Registers of medical laboratory specialists exist. In some countries several registers exist, depending on the academic background of the medical laboratory specialist. Such National Registers may apply for EC4RC Recognition of Equivalence of Standards. In some EU countries no national register exist and EC4 encourages and helps these countries to set up such a Register. Colleagues from all relevant academic background, scientific as well as medicine, pharmacy, veterinary, and other, if registered in their National Register can and do apply for registration in the EC4 register. The name 'Clinical Chemist' causes confusion and inhibits some colleagues from applying. Therefore the name was changed into *European Specialist in Clinical Chemistry and Laboratory Medicine* in 2002, keeping, however, the existing abbreviation Eur-ClinChem.

*Operation.* To set up the register, EC4 installed a register commission (EC4RC) in 1997. The Register was opened in 1998. Each society was invited to send one delegate from the National Clinical Chemistry Registration Commission (NCCRC) to EC4RC. A board was elected and the structures for the operation of the register were developed. The operation of the register is based on the European Syllabus (2), defining the necessary items of postgraduate education, the Guide to the Register (3), giving the basic education and the rules for entering the register, and the Code of Conduct (4), defining the criteria of behaviour of professionals in our discipline.

The EC4 Register is based on the Recognition of Equivalence of Standards to national registers by the EC4 Registration Committee and the EC4 Board. A major task for the EC4RC will be the co-operation with and inclusion of the new countries. During the next few years the recognition of equivalence of standards of the national registers should be renewed for all countries, both old and new EU member states. The criteria which are used for recognition will be revised. Terms of reference and the final attainment level have been defined (5). The way training sites are inspected will be part of the criteria for recognition including checklists for assessors and procedures for assessment or inspection.

National Register committees are keeping the national registers and are asked to keep EC4RC well informed about the national education and training

structure. If more than one national register exists, e.g. for different academic backgrounds, EC4RC expects a joint representative from that country. Following the guide to the register, EC4RC acknowledges those national registers that meet the requirements of the Syllabus and other criteria. Individual applications have to be voted by both NCCRC and EC4RC. If there is no national post graduate education and no national register organised, EC4RC encourages and assists the national society to set up such register. Applications from such member state are considered on an individual basis.

A third revision of the Syllabus will be prepared.

The minimum number of years of training and experience was recently extended from eight years to nine, i.e. four or five years academic plus four or five years postgraduate specialist training, in total nine years.

A new Code of Conduct was published in 2004 (4). Consent to the Code should be part of the criteria used by the national registers and by the EC4RC. The Code will play an important role in new EU directives relating the common values of regulated professions, like the proposed directive on Recognition of Professional Qualifications.

The EC4RC contributes actively in co-operation with the working group on Profession to achieve that the EC4 Register becomes a Common Platform within the framework of the EU Directive on Recognition of Professional Qualifications.

*Re-registration.* Re-registration is becoming an issue in many countries. Initial registration as European Specialist in Clinical Chemistry and Laboratory Medicine is granted for five years. The first applicants should re-register starting from 2005. The system for re-registration should be further developed, starting by using existing national systems. Continuous professional development will be part of the criteria for re-registration. Further guidelines for terms for such systems will be issued.

#### *Common Platform*

The free exchange of goods and services and the freedom of movement within the European Union include the free exchange of professionals between all member states. To make sure that the competence of all specialists in clinical chemistry and laboratory medicine fulfils a common minimum standard EC4 agreed to promote recognition of the profession by establishing a European register. The main goal is to achieve recognition of the EC4 Register as a so-called Common Platform by the European Commission and the EU Member States within the framework of the EU Draft Directive on Recognition of Professional Qualifications. EC4 is active to convince the Commission of the necessity to recognise a system of

Common Platforms governed by the professions under the supervision of a General European Board of National Co-ordinators. The EC4 Register should become such a Common Platform. The European Parliament and the European Commission have voted in favour on the draft directive in second reading. National politicians should now be motivated to vote in favour. The position of specialists in clinical chemistry and laboratory medicine and how clinical chemistry and laboratory medicine is organized in Europe (5) should be explained as well as the necessity of a Common Platform. The co-operation with CEPLIS and the European Economic and Social Committee to achieve a Common Platform will be extended.

### **Performance of the profession**

#### *Competence to be a Consultant*

A working group was installed to define guidelines concerning duties and competences of heads of clinical chemistry laboratories and senior consultants. The working group has produced a Guide to Defining the Competence Required of a Consultant in Clinical Chemistry and Laboratory Medicine (6).

#### *Patient information*

There is a definite need for information among patients and the public in general. Sites like Lab Tests Online (UK and The Netherlands) are gaining increasing interest. Developments like the patient questions platform in the Netherlands are frequently used media. A working group will be installed to provide guidelines and help for national organisations to set up web sites in the native language like Lab Tests Online and Information and questions for the public.

### **Performance of laboratories (CARE for laboratories)**

#### *ISO/CEN*

EC4 co-ordinates and promotes the voice of professionals in the relevant CEN and ISO committees and working groups to improve the influence of the profession on the development of standards, that influence directly our work. The chair of the EC4 WG presently is chair of ISO TC212 WG 1 and EC4 is happy to support him. Focus will be on the revision of ISO 15189. Several EC4 publications (7–9) contributed to the development of the ISO 15189 International Standard, which defines requirements for quality and competence of medical laboratories. Now that this is a published standard, the WG will co-ordinate the input for the next version of it. Attention will be given also to other documents under development, in particular regarding POCT and Safety. The working group should also contribute in the monito-

ring of the implementation of the EU IVD directive. Different interpretations in individual countries of the IVD Directive ruling on in house testing, threatens expert centres and new or commercially not interesting tests. The working group should monitor new developments in ISO and CEN which influence medical laboratories and should inform national societies on these developments.

#### *Quality Systems and Accreditation*

EC4 co-ordinates activities towards the European co-operation for Accreditation (EA) and national accrediting organisations, with regard to mutual recognition of accreditation systems for medical laboratories. Several colleagues in the working group on Accreditation have a seat on the EA committee on Laboratory Medicine, including the representative from EC4/FESCC. The input from the profession in the committee will be co-ordinated in the WG. The focus of the WG will be on the use of ISO 15189 as the standard for accreditation.

The EC4 Essential Criteria (7, 8) are widely used as practical guidelines for implementation of quality systems in medical laboratories. The EC4 Model Quality Manual (10) is a further tool to help individual laboratories to set up their quality system.

Criteria for inspections of medical laboratories as well as for assessors will be defined. Advice will be given on the co-ordination of exchange of accreditation inspectors between EU countries. Additional Essential Criteria will be defined regarding continuous quality improvement, systems for document control, retention time of specimens, archiving of documents, retention time of records. Guidelines on method validation will be issued, and guidelines on expressing uncertainty of measurements. The specific nature of the medical laboratory requires essential criteria for clinical audit in laboratory medicine. Also criteria for internal audit including audit checklists are needed.

### **Performance of laboratories (CARE for laboratory data)**

#### *Guidelines for Investigation of Disease*

One of the main responsibilities of our profession is to give advice on the use and interpretation of laboratory data. There exist many books and publications regarding this subject. In a unifying Europe it is important to have (European) Guidelines on the Laboratory Investigation of Disease. The working group GID functions as a steering group. It initiates multi-disciplinary project groups on specific topics, including experts from the laboratory discipline as well as from the clinical side. The guidelines should be evidence based. Co-operation is sought with existing organisations like the Guidelines International Network (GIN). EC4 is active in this field in co-operation

with FESCC and other European organisations in laboratory medicine, and in particular also other European medical specialists' organisations, to publish such guidelines. Guidelines were published on inherited thrombophilia (11). The project group on IVD effects on creatinine result interpretation was started in 2004. A project group on guidelines for cardiac disease was started in 2005.

A guideline database including primarily laboratory, or lab-related guidelines would be extremely useful. There are many guidelines, but it is quite often difficult to find special recommendations within guidelines on the use of lab tests. Such an information resource will be developed.

#### *EQUAL*

In 2004 the first meeting of the EQUAL project took place. The EQUAL project was initiated by EC4 and aims at the development of a European quality assessment scheme and training courses in Nucleic Acid Testing in clinical chemistry laboratories. The project obtained a Grant from the European Commission. The project results will be published in 2006–2007.

#### *Desirable Analytical Performance*

The joint FESCC/EC4/EDMA working group on desirable analytical performance will define Essential Criteria concerning clinically relevant analytical requirements, based on published work and in relation to the EU IVD directive. Another important field is unified acceptance limits for EQAS, based on the above. In a joint EU, it is important to harmonise these limits.

#### *Calibration of data*

EC4 stimulates developments for harmonisation of laboratory data. The Calibration 2000 project (12–14) of The Netherlands is such a project. The materials developed in this project are commutable with patient materials and should be tested on an international base to investigate their potency as Trueness Verification Materials. The EU IVD directive requires traceability to reference systems. Verification of such traceability requires commutable materials and international co-operation between NEQAS organizers and national societies. It is the responsibility of the medical laboratory specialist to estimate within and between laboratory variations and to decide whether correction for observed bias is needed in a particular laboratory situation. This could be done in co-operation with the industry. For such corrections commutable trueness verification materials are necessary. EC4 will continue to stimulate projects in this field.

## **Profiling towards European bodies and organisations**

### *Co-operation with other European organisations*

*FESCC.* In order to improve the image and functioning of laboratory medicine in Europe, co-operation between the various European umbrella organisations is important. The EC4 Executive Board will put effort in maintaining and extending such co-operation. EC4 is an autonomous working group within FESCC. All of the EC4 work and documents are sent to and available for FESCC. The boards of FESCC and EC4 maintain a close working relationship. The future relationship of FESCC and EC4 should be considered in the light of the recent enlargement and future enlargement of the European Union. As more European countries join the EU, the two organisations should work towards becoming a single organization. In 2005 a proposal for a merger of the two organisations was presented at the Euro-medlab congress in Glasgow. In the new organisation the active nature and the productivity of EC4 should be conserved.

*Other professional umbrella organisations.* EC4 strives for co-operation with other European umbrella organisations in laboratory medicine, such as UEMS section Bio-pathology.

EC4 should re-consider its position regarding a European Platform of Laboratory Medicine and the co-operation with other umbrella organisations in laboratory medicine.

Professional involvement in the different EU bodies which deal with aspects of clinical chemistry and laboratory medicine is essential. The importance of clinical chemistry and laboratory medicine, in its broad definition as defined in the Guide to the European Register, and all activities performed in EC4 must be more widely known in the EU official bodies. EC4 will seek contact with the European Commission to clarify the importance of clinical chemistry and laboratory medicine in all its aspects for the improvement of patient care in the EU. Therefore it is essential to maintain a list of all EU-bodies relevant to and dealing with the medical laboratory profession. This will facilitate the recognition of the European Register and EC4 views on accreditation. The extension of the EU is an exciting challenge for EC4. EC4 will see to a firm integration of the new countries in the EC4 work.

*European Commission.* The monitoring of EU draft directives and their consequences for the me-

dical laboratory professionals and medical laboratories is an important task for EC4. EC4 co-ordinates activities and communicates developments to the national societies. Regulations of direct importance at present are the draft directive on recognition of professional qualifications, the draft directive on services in the internal market, the directive providing an information procedure in the field of technical standards and regulations, the EU Questionnaire on the common values of the regulated professions in Europe, and the IVD directive.

*ISO, CEN and EA.* EC4 realises that it is difficult for national societies to keep up to date with the various international standards, draft standards and documents of ISO, CEN and other bodies. The notifying of member societies of current developments in CEN and ISO will be structured. The WG will produce simple guidance documents to assist national societies in understanding and applying ISO/CEN documents. EC4 continues to encourage the national societies to find their way to the National Accreditation Bodies and Standardisation Institutes. Within the working group on ISO/CEN a network has been established to share experience and co-ordinate influence on CEN and ISO working groups and on EU directives. With regard to accreditation EC4 will continue to influencing the European co-operation on Accreditation (EA).

*EDMA.* Co-operation with the industry is important in scientific matters, EU regulations and directives, accreditation, and quality requirements and assessment. EC4 should be in close contact with EDMA.

*Web site.* The communication of EC4 activities towards member societies, European Commission, the medical profession in Europe, the public in Europe, industry and relevant European organisations is extremely important and will be extended. The EC4 website (15) plays an important role in the providing of information.

## **Conclusion**

EC4 is the organisation in the European Union for clinical chemistry and laboratory medicine. It has proven to be a productive organisation and the national societies have recognized its importance by nominating and supporting members of the large number of working groups. The work of these working groups is gratefully acknowledged by EC4 Executive Board. It is the true base for the development of our profession in Europe.

## EC4: SADAŠNJE I BUDUĆE AKTIVNOSTI

*Rob Jansen*

*Clinical Laboratory, St. Anna Hospital Geldrop,  
5660 AB Geldrop, The Netherlands*

*Kratak sadržaj:* EC4 je organizacija za kliničku hemiju i laboratorijsku medicinu u Europskoj uniji. Osnovni ciljevi EC4 su prepoznavanje profesionalnih kvalifikacija, uticaja ISO i CEN dokumenata koji su vezani za profesiju, praćenje EU direktiva važnih za profesiju, dostizanje ekvivalentnosti standarda pri akreditaciji medicinskih laboratorija u Evropi, definisanje uputstava za laboratorijsko ispitivanje oboljenja i harmonizaciju laboratorijskih podataka preko kalibracije. Evropski registar za specijaliste kliničke hemije i laboratorijske medicine uspostavila je EC4 registraciona komisija. Brojne radne grupe su aktivne u dostizanju postavljenih ciljeva. U ovom radu opisane su sadašnje i buduće aktivnosti.

*Ključne reči:* Evropa, profesionalne kvalifikacije, registar, kvalitet, akreditacija, kalibracija, uputstva

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15. EC4 web site <http://ec-4.org>

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