Recent Activities of EC4 in the Harmonization of Clinical Chemistry in the European Union

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Introduction

In this article the progress of activities of the European Communities Confederation of Clinical Chemistry (EC4) will be explained.

The confederation was formally instituted on April 27, 1993 in Nice (France). Before that date, informal contacts between the clinical chemistry societies in the European Union (EU) had existed since the seventies. Already at that time, visions about the practice of clinical chemistry in the different EU countries were exchanged. Common aspects concerning the national contents of or profession, professional post-graduate training, quality assurance systems and other issues were addressed. It was hoped to obtain a specific directive for clinical chemistry from the European Commission in Brussels, but this effort failed and finally was stopped.

What did not end, and even was strongly reinforced, was the work on harmonization of our profession, especially after the official foundation of EC4 (1).

Since EC4 is the organization of societies for clinical chemistry in the EU, the EC4-board consists of representatives of the national European Union societies for clinical chemistry. All these societies are members of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and its European branch, the Forum of European Societies of Clinical Chemistry (FESCC). The structure of EC4, based on membership of EC4 by national societies, means that individual professionals cannot be members. The contact with EC4 exists only via their national IFCC-affiliated societies.

Goals

The main goal of EC4 is harmonization of clinical chemistry in the European Union in particular and Europe in general. It is the aim of EC4 to improve the quality of all aspects that comprise clinical chemistry in the EU, and this of course can be accomplished best and foremost by raising the level of the quality of the individual professionals. That may influence clinical chemistry in a positive way and bring the practice of clinical chemistry more into one line. For that the EU has chosen the mechanism of harmonization. This we consider not to be the same as unification, since EC4 wishes to respect the way clinical chemistry is performed and has devel-
op ed itself within the national health care systems. By doing so we try to learn from each other’s national systems, and EC4 hopes to be able to recognize the best elements of clinical chemistry in the separate countries to bring them into practice in the whole EU.

Under the umbrella of harmonization, EC4 set itself two main tasks: the quality of the laboratory and the quality of the professional. These two main goals are interlinked and in themselves consist of a number of minor aspects.

For the quality of the professional, the initiative for the European register of Clinical Chemists was developed. For the quality of the clinical chemistry laboratory, as for other disciplines in health care, accreditation is the recognition of the status of the overall diagnostic process. One of the conditions for recognition of excellence of a laboratory is that the professional contribution is of the highest possible, and proven, level. So, accreditation cannot be complete without relevant training of professional staff and technicians. This is where European registration and accreditation together serve the interest of patients for whom we perform our activities.

**European Register**

The institution of the EU Register for Clinical Chemists is one of the best ways to regulate the profession of clinical chemistry, since it is based on a common EU training program. That is where harmonization should start. The activities EC4 has undertaken to reach this goal in the past years are publication of the European Syllabus for Postgraduate Training, the proposal for a so called sectorial directive for clinical chemists in the EU, and the institution of a European Register for Clinical Chemists.

Clinical chemistry in the EU is practised by some 35000 professionals and the estimated total annual turnover is 15 · 10⁹ Euro. The background of these professionals and the estimated total annual institutional directive for clinical chemists in the EU, and the institutionalization of excellence of a laboratory is that the professional contribution is of the highest possible, and proven, level. So, accreditation cannot be complete without relevant training of professional staff and technicians. This is where European registration and accreditation together serve the interest of patients for whom we perform our activities.

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For the profession of clinical chemistry, the advantages of a European Register are: the profile of clinical chemistry is raised within the EU; common high standards of education, training and experience, and compliance with continuing professional development are instituted. Moreover, comparability of professional training, and of content and practice of clinical chemistry is facilitated, improving mobility.

The Register is beneficial to the patient (and employer), since it guarantees adequate professional training, and assures adherence to the Code of Conduct added to the Register.

The European Register is kept by the EC4 Register Commission (EC4RC), advised by the National Clinical Chemistry Register Committees (NCCRC). Another important task for the NCCRC is to guarantee the equality of the vocational training at a national level.

A clinical chemist wishing to register sends an application with personal details and a curriculum vitae to the NCCRC. This committee keeps the national register and assesses the suitability of the candidate. After recommendation, the final decision is at the EC4RC. Registration in the EC4 Register leads to the title EurClinChem.

Application is open for EU citizens trained within EU, clinical chemistry in the EU based on the harmonization of vocational training in clinical chemistry in the European Union by way of a European Register for Clinical Chemists. The initiative of the European Federation of National Engineering Associations (FEANI) has served as a model for EC4. According to the European Commission this is an excellent example of self-regulation by a profession at the European level (2).

The EC4 European Syllabus for Postgraduate Training forms the basis for the European Register. It is not a training guide as such, but must be seen as an indication of the level of requirements in postgraduate training and the content of national programs needed to obtain appropriate knowledge and experience. It is a common minimal program approved by all EU societies of clinical chemistry and leaves undisturbed the different structures of medical laboratories as developed in their national environments. Some of its core elements are: knowledge in clinical chemistry, hematology, bloodbanking, immunology, etc.; pre-analytical conditions; analysis and methodological evaluation of analytical findings; medical interpretation of analytical findings; clinical training; research and development; laboratory management and quality assurance. Such a syllabus is the reflection of a profession of which the contents are changing continuously. Therefore, it needs to be updated regularly.

A guide to the EC4 Register has been published. Registration will lead to the title of European Clinic Chemist (EurClinChem) (3, 4). A European Register has advantages for the individual professional, the profession, and the patient. The individual professional can prove to be a qualified clinical chemist, may use the title EurClinChem, is recognized at least by all clinical chemistry societies, all over the European Union even where under local law no protection exists, and free movement within the EU is facilitated.

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EU citizens trained outside EU, and non-EU citizens trained within the EU. Non-EU citizens not trained in an EU country are not eligible for registration.

The present status of the Register is that it was launched after the publication of the documents as mentioned in references 3 and 4. Also, an information leaflet has become available.

The first certificates to European Clinical Chemists were granted in Helsinki on October 3, 1998. In the meantime over 50 colleagues have been registered.

For more information, the EC4 website may be consulted (5).

Accreditation of Laboratories

There is an increasing awareness in medical laboratories of the need of total quality management. After a long history of the use of internal quality control and external quality assessment schemes, there is now the requirement for control of the complete laboratory process. An important tool to achieve such control is a total quality management system.

However, as far as accreditation of laboratories is concerned, the situation is different from that of vocational training. No EC4 accrediting body exists, and EC4 does not wish to fulfill that role. It only has tried to describe the guidelines (Essential Criteria) which it judges appropriate for establishing the quality of laboratory service. Thereby EC4 focuses on medical laboratories in general because in most EU countries clinical chemistry is a polyvalent discipline. With the Essential Criteria, EC4 wishes to support international standardization organizations like CEN and ISO in the development of documents concerning quality of medical laboratories. It is hoped that accrediting bodies in the EU will proceed along these lines when judging quality systems present in laboratories. In these the whole process from pre-analytical stage to interpretation has to be included. That means that EC4 is strongly of the opinion that medical laboratory accreditation must be service-based rather than test-based.

A quality system requires a quality manual to be compiled, describing the organization of the laboratory including functionality and the responsibilities of staff. Operating procedures would describe pre-analytical, analytical and post-analytical activities.

Pre-analytical aspects include consultation on appropriate investigations, patient preparation for sampling, and sample collection techniques. Analytical aspects include procedures for calibration, analysis, internal quality control and external quality assessment. Post-analytical aspects include procedures for authorization, timely and accurate reporting, and consultation on the interpretation of results in relation to diagnosis, treatment, prognosis and further investigations.

There are international standards for certification (ISO 9001) and for accreditation (EN 45001 and ISO Guide 25). However, these standards are either very general (ISO 9001), or are developed for testing and calibration laboratories (EN 445001, ISO Guide 25), and therefore do not address the specific aspects of the work of medical laboratories. The scope of medical and clinical laboratories is different from these laboratories and needs additional criteria.

The Working Group on Harmonization of Quality and Accreditation Systems of EC4 has prepared a set of documents describing essential criteria for quality systems in medical laboratories to clarify the specific needs (6–10). Clinical laboratories that have implemented quality systems based on the Essential Criteria fulfill all criteria for accreditation. EC4 considers this as a European Union-harmonized accreditation system. This document provides guidelines for implementation of total quality systems in medical laboratories. It is easily applicable to multidisciplinary and other types of medical laboratories. The quality systems of medical laboratories would reflect the special tasks of such laboratories. Therefore, the emphasis of the document is on all previously described phases and on efficacy and efficiency of requested investigations.

A medical laboratory that has implemented a quality system according to the criteria described in the EC4 document fulfills ISO 9001, EN 45001 and ISO Guide 25 standards that are relevant to medical laboratories, and is prepared for accreditation or certification by all relevant schemes. Particular schemes originating from the professions, although operating independently, such as the Belgian system, CCKLtest in the Netherlands, CPA in the United Kingdom, the French GBEA system, are suited for such accreditation. Guidelines published by these organizations are in agreement with the present international documents, and the Handbooks and Model Quality Manuals based on the guidelines and issued in these countries are of use for laboratories wishing to implement a quality system.

The new ISO Committee Draft document 15189 recognizes the special position of medical laboratories much better than the ISO 25 Guide. The EC4 Essential Criteria have strongly influenced the contents of this draft document. From it the following text is derived: “Medical laboratory services, including appropriate consultation services, are essential to patient care and therefore should be available to meet the needs of all patients, their physicians, and other clinical personnel responsible for patient care. Specific functions include requisition, patient preparation, collection (where applicable), proper identification, transportation, storage, processing, and examination of clinical samples with subsequent reporting of results. When necessary, medical laboratory services should include the examination of patients in consultation cases and active participation in prevention, diagnosis, and management of patients. Each service should also provide suitable educational and scientific opportunities for the academic and technical staff. Governmental bodies may provide licence to a medical laboratory to do certain examinations (tests) on specified conditions.”

The Executive Board of EC4 therefore recommends that ISO/CD 15189 “Quality Management in the Medical Laboratory” be supported as a reference document for laboratory accreditation. Its final version should be
considered together with the EC4 document as Essential Criteria when defining a national scheme for laboratory accreditation.

As an extension of its activities in the field of accreditation, EC4 has recently also taken the initiative to create a working group investigating the possibilities for a European co-operation for Accreditation of Medical Laboratories (ECAML). This might be a commission to harmonize the work of national accreditation bodies, preferably within the European co-operation for Accreditation.

**Activities of CEN and ISO**

EC4 considers it also one of its tasks to monitor the activities of the different standardizing bodies that might influence the practice of clinical chemistry. The main ones are ISO/TC 212 Working group I and CEN/TC 140. The former is concerned with accreditation, the latter with in vitro diagnostics and quality. A newer document on accreditation is ISO Committee Draft 15189 on quality management in the medical laboratory, as mentioned earlier. It is advised to every national clinical chemistry society to take notice of these activities and to transfer the results to the relevant national standardizing bodies.

**Future Strategy**

The EC4 strategy document has been prepared now, and will be put to the next General Assembly.

The key words for future activities of EC4 will remain clinical chemistry in its broadest sense, European Union and harmonization. At present professional training, education in a broad sense and accreditation, fall within these domains.

Within these boundaries, the work on the register, the syllabus, and the accreditation will continue, and EC4 will judge the consequences of activities of CEN and ISO for our profession. In relation to these key items, four aspects may be discerned: profession (regulation), performance of clinical chemistry, performance of laboratories, and profiling of clinical chemistry.

The profession now has an established register and re-registration will be an issue for the future. Also the European Syllabus, which will always form the basis of the register, should be updated regularly. That is essential in a dynamic profession such as ours.

The performance of the profession will profit most from strategies for interpretation of test results, diagnostic strategies, and clinical decision making and evidence-based laboratory medicine. It is the intention of EC4 to set up a new working group on guidelines related to these issues.

The performance of laboratories can be based on the Essential Criteria that the EC4 Working Group on Accreditation has published. Harmonization of national systems for accreditation of medical laboratories will lead to general EU qualifications for heads of clinical chemistry laboratories, advised requirements for their organization and quality assessment schemes, and the level on which they perform their services. EC4 expects that the co-ordination of accreditation activities may finally lead to an inter-European exchange of accreditation inspectors.

Profiling of clinical chemistry and of EC4 in the EU will be necessary once EC4 has results of its activities to show. The promotion of the EC4 website at the Internet (5) may support this. Also, the extension of the European Union will force EC4 to orient itself to the practice of clinical chemistry in candidate member states. EC4 realizes that its activities may influence the position of professionals in other, non-EU, countries. Therefore, a cooperation with FESCC will remain essential.

The strategy document mentioned above contains a number of actions related to these issues to prepare EC4 for the years to come.

**References**


5. EC4 website: http://www.uni-oldenburg.de/ec4.


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