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The EC4 register of European clinical chemists and EC4 activities

Rob T.P. Jansen

Department of Clinical Chemistry, St. Anna Hospital, P.O. Box 90, NL-5660 AB Geldrop, The Netherlands

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Abstract

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 recognize, or if necessary obtain, 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. European Communities Confederation of Clinical Chemistry (EC4) is the organization of societies for clinical chemistry and laboratory medicine in the EU. In Europe, health care develops in the direction where patients are treated in a health care chain environment. 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 including several laboratories. Diagnosis and therapy are now 'core business' of health care. Medical laboratories play an essential role in this. The broad spectrum of medical laboratory investigations make consultancy of medical laboratory specialists ever more important. The quality of both professionals and laboratories, as well as continuity of laboratory data within and between laboratories, are of utmost importance. EC4 is active in giving support to attain such quality. In most countries, this is the case at present. EC4 plays a central role in the Coordination of Automatic Recognition of Equivalence of Standards (CARE), if such a level exists or is achieved. Such CARE is focussed at three levels, the profession, quality of laboratories and calibration of laboratory data. The EC4 Register of European Clinical Chemists is open for colleagues educated in (bio)chemistry, pharmacy, biology as well as medicine, and trained according to the EC4 Syllabus. Equivalence of standards has been granted to national training schemes of 13 European Union countries. Since its opening in 1998, the number of applicants is growing steadily and quickly, reaching 1225 in May 2001. EC4 has published essential criteria for quality systems of medical laboratories, which formed the basis for a ISO draft international standard regarding quality and competence of medical laboratories. EC4 stimulates projects like the Calibration 2000 project in the Netherlands which focus on continuity of laboratory data, within — as well as between — laboratories.

Keywords: European Union; Recognition; Quality of care; Quality of profession; Medical laboratories

1. 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 recognize, or if necessary obtain, 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 International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) related National Societies of Clinical Chemistry in EU countries. The common political

E-mail address: r.jansen@st-anna.nl (R.T.P. Jansen).

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reality led to the institution of the European Communities Confederation of Clinical Chemistry (EC4).

EC4 is the organization of societies for clinical chemistry and laboratory medicine in the EU. The EC4 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, the Forum of European Societies of Clinical Chemistry and Laboratory Medicine (FESCC).

In Europe, health care develops in the direction where patients are treated in a health care chain environment. 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 including several laboratories. Diagnosis and therapy are now 'core business' of health care. Medical laboratories play an essential role in this. The broad spectrum of medical laboratory investigations make consultancy of medical laboratory specialists ever more important. The quality of both professionals and laboratories, as well as continuity of laboratory data within and between laboratories are of the utmost importance.

EC4 is active in giving support to attain such quality. It is important that laboratory medicine is practiced at an adequate level throughout Europe.

In most countries, this is the case at present. EC4 plays a central role in the Coordination of Automatic Recognition of Equivalence of Standards, if such a level exists or is achieved. The Coordination of Automatic Recognition of Equivalence of standards (CARE) should be reached at three levels:

- CARE for the profession,
- CARE for quality of laboratories,
- CARE for calibration of laboratory data.

2. CARE for the profession

The installation of the EC4 Register of European Clinical Chemists is a large 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 education of the medical laboratory specialist. Colleagues from all relevant academic background, scientific as well as medicine, pharmacy, veterinary and others, may and do apply. The EC4 Register is based on the Recognition of Equivalence of Standards to national registers by the EC4 Registration Committee and the EC4 Board.

The free exchange of goods and services and the freedom of movement within the European Union includes the free exchange of professionals between all member states. To make sure that the competence of all clinical chemists fulfils a common minimum standard the European Communities Confederation of Clinical Chemistry (EC4) agreed to promote recognition of the profession by establishing a European register. The operation of the register is based on the European Syllabus [1] defining the necessary items of postgraduate education, and the Guide to the register [2,3], giving the basic education and the rules for entering the register.

To set up the register, EC4 installed a register commission (EC4RC) in 1997. Each society was invited to send one delegate to EC4RC. A board was elected and the structures for the operation of the register were developed. National register committees are keeping the national registers and are asked to keep EC4RC well informed about the national education and training structure. Applicants may appeal against EC4RC decisions to the EC4 Committee of Appeal.

Following the guide to the register, EC4RC acknowledges the national registers if they meet the requirements of the Syllabus. Individual applications have to be voted by both NCCRCs and EC4RC. If there is no national post graduate education and no national register organised, EC4RC considers application on an individual basis. The register was opened in 1998 [4].

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, blood-banking, immunology, etc.; knowledge on pre-analyt-

ical aspects including consultancy regarding requesting; analysis and methodological evaluation of analytical findings and interpretation of data; 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 second version has been published recently [1]. The Syllabus is the basis of clinical chemistry in Europe.

The context of clinical chemistry differs for different countries (Table 1). In many countries, clinical chemistry is practiced on a polyvalent base in contrast to the much more narrow practicing in the US. The polyvalency is covered by the Syllabus.

To enter the training a university degree is demanded. In the European Union, the university education for MDs averages to 5–6 years, range 4–7 years. For PhDs, the average university education (biology, biochemistry, chemistry or pharmacy) is 5.5 years, range 4–7 years. Postgraduate training for MDs and PhDs is 5–7 years on the average, range 4–8. The minimum standard for the European Register is at present 8 years of study after entering the university (BAC + 8).

Official legal national registers for MDs exist in all EU countries except for Germany, Ireland and Italy. For PhDs legal national registers do not exist in Austria, Denmark, Germany, Greece, Ireland, Italy and The Netherlands. In several countries, voluntary society linked registers exists.

The EC4 Registration Commission keeps the European Register. Members are representatives of the National Clinical Chemistry Register Committees. The EC4RC is responsible for the European Syllabus. On the basis of the Syllabus, it grants Equivalence of Standards to national training schemes. Equivalence of standards has been granted to national training schemes of 13 European Union countries. The EC4RC considers and decides on individual applications that are not straightforwardly accepted by the EC4RC board.

2.1. Operation of the register

The guide to the Register [3] describes the operation of it. Applicants send in the application form plus their CV to the NCCRC. The NCCRC forwards these to the EC4RC president including a recommendation. The EC4RC president judges the application. If the national register has been granted Equivalence of Standards, if the NCCRC recommendation is positive and if the CV proves that the applicant is still professionally active, the EC4RC board automatically accepts the application. Registration in the EC4 Register leads to the title European Clinical Chemist for the applicant. If the recommendation of an

Table 1
Content of clinical chemistry in the European Union countries

	Clinical (bio) chemistry			Microbiology	Blood banking
	Clinical chemistry	Hematology	Immunology		
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**
Luxemburg	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**	**no**
United Kingdom	yes	**no**	**no**	**no**	**no**

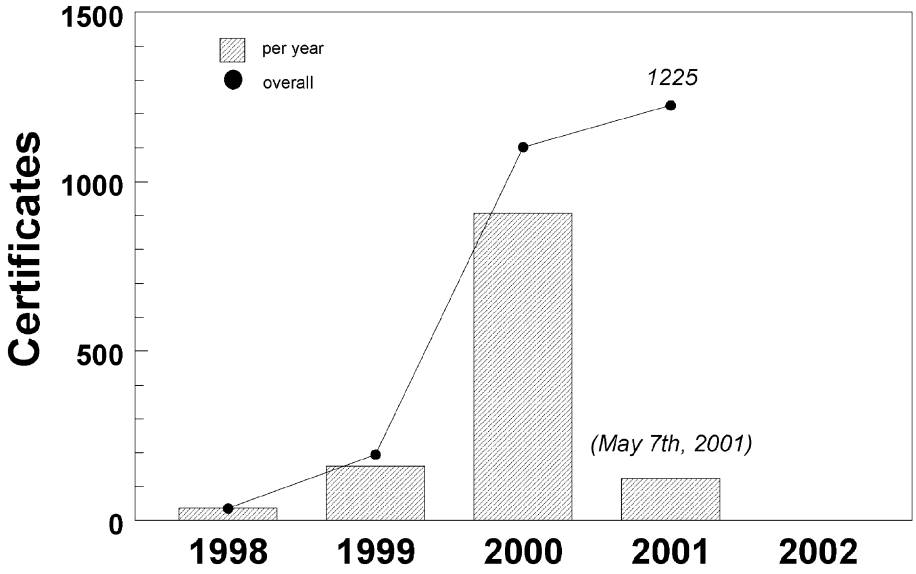

Fig. 1. Number of EC4 European Clinical Chemist certificates per year and cumulative. After the advise of the European Commission to the Ordre de Pharmaciens in France, the number of French biologistes cliniques applicants increased greatly.

NCCRC having Equivalence of Standards is negative the application will be discussed by the EC4RC and be rejected. If the application comes from a country of which the NCCRC has not been granted Equivalence of Standards, the application will be considered by the EC4RC.

The first European Clinical chemist certificates were granted in October 1998. On May 2001, 1225 certificates have been granted.

The number of applications from most European Union countries is increasing steadily (Fig. 1). The number of applications from France is growing more

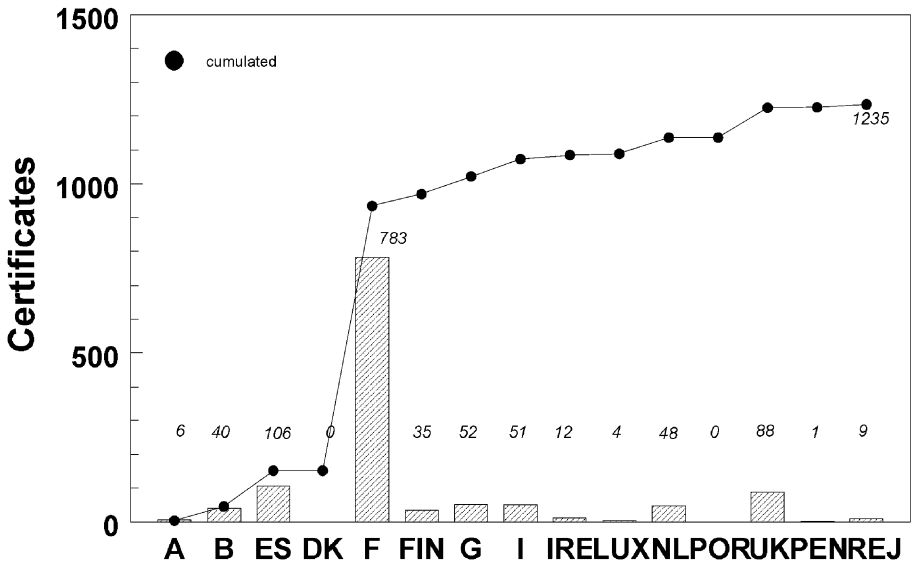

Fig. 2. Number of certificates per country.

quickly and exponentially (Fig. 2) after the recommendation of the European Commission to the L'Ordre des Pharmaciens that the EC4 Register will be considered as the European Register for Biologistes Cliniques [5]. The European Commission is in a process of changing the Sectorial Directives and the General Directive regarding Professional Recognition. 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 Coordinators. The EC4 Register and the FEANI Register of European Engineers are the first examples of such Common Platforms.

2.2. Number of consultants

EC4 is working on a guideline for the desirable number of consultants. A working group is presently making an inventory of the existing situation regarding the number of consultants practicing in medical laboratories in the EU. The working group also makes an inventory of existing national guidelines and legislation.

3. CARE for laboratories

EC4 coordinates activities for recognition on the basis of accreditation standards for medical laboratories. Several publications [6–8] have contributed to the development of the ISO 15189 draft International Standard related to quality systems and competence of medical laboratories. The EC4 Essential Criteria are widely used as practical guidelines for implementation of quality systems in medical laboratories. A Model Quality Manual is a further tool to help individual laboratories to set up their quality system [9,10]. EC4 coordinates 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.

4. CARE for calibration of data

EC4 stimulates developments for harmonisation of laboratory data. The Calibration 2000 project of The Netherlands is such a project [11]. The materials developed in this project are commutable with patient materials and should be tested on an international base to investigate their potency as international secondary reference materials. In the Reference Systems [12] needed for the implementation of the In Vitro Diagnostics directive of the European Union, there is a need for commutable secondary reference materials. Such materials should be available for industry as well as profession. It is the responsibility of the professional to estimate within and between laboratory variations and to decide whether correction for observed bias is needed in a particular laboratory situation. For such corrections, commutable secondary reference materials are necessary.

5. Conclusions

EC4 is active in several fields regarding clinical chemistry and laboratory medicine. Coordination for automatic recognition on the basis of equivalence of standards is one of the goals. Particularly the EC4 Register is an important development. The European Commission has advised to the Ordre des Pharmaciens in France that biologistes cliniques apply for this register, thus obtaining the title European Clinical Chemist. The register is open for colleagues educated in (bio)chemistry, pharmacy, biology as well as medicine, and trained according to the EC4 Syllabus. Since its opening in 1998, the number of applicants is growing steadily and quickly, reaching 1225 in May 2001.

The authorities and the public demand demonstrable quality. This is and will be particularly important in health care. Laboratory medicine has evolved into a core discipline in diagnosis. It is essential that laboratory information is provided with the highest quality. Such quality requires appropriately educated and trained consultants as well as adequately functioning laboratories. EC4 has published essential criteria for quality systems of medical laboratories, which formed the basis for an ISO draft international standard regarding quality and competence of medical laboratories.

There is a need for commutable secondary reference materials to harmonize laboratory data. Continuity of laboratory data makes the absence of bias and stability in time increasingly important. Also the developments in health care in which patients are

treated in health care chains, often involving primary, secondary and tertiary institutes, many physicians and several laboratories, requires harmonization of laboratory data between laboratories. EC4 stimulates projects like the Calibration 2000 project in the Netherlands which focus on this topic.

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