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# The EC4 register of European clinical chemists and EC4 activities

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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. EC4 stimulates projects like the Calibration 2000 project in the Netherlands which focus on continuity of laboratory data, within—as well as between—laboratories. © 2002 Published by Elsevier Science B.V.

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

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45 EC4 is the organization of societies for clinical che- 90  
46 mistry and laboratory medicine in the EU. The EC4 91  
47 executive board consists of representatives from the 92  
48 societies. The EC4 member societies are members of 93  
49 the IFCC as well of its broad European regional 94  
50 branch, the Forum of European Societies of Clinical 95  
51 Chemistry and Laboratory Medicine (FESCC). 96

52 In Europe, health care develops in the direction 97  
53 where patients are treated in a health care chain en- 98  
54 vironment. In this chain, patients move quickly from 99  
55 primary health institutes to secondary and tertiary 100  
56 institutes, and vice versa. This situation involves many 101  
57 health care workers including several laboratories. 102  
58 Diagnosis and therapy are now 'core business' of 103  
59 health care. Medical laboratories play an essential role 104  
60 in this. The broad spectrum of medical laboratory in- 105  
61 vestigations make consultancy of medical laboratory 106  
62 specialists ever more important. The quality of both 107  
63 professionals and laboratories, as well as continuity of 108  
64 laboratory data within and between laboratories are of 109  
65 the utmost importance. 110

66 EC4 is active in giving support to attain such 111  
67 quality. It is important that laboratory medicine is prac- 112  
68 ticed at an adequate level throughout Europe. 113

69 In most countries, this is the case at present. EC4 114  
70 plays a central role in the Coordination of Automatic 115  
71 Recognition of Equivalence of Standards, if such 116  
72 a level exists or is achieved. The Coordination of 117  
73 Automatic Recognition of Equivalence of standards 118  
74 (CARE) should be reached at three levels: 119

- 75 • CARE for the profession, 120
- 76 • CARE for quality of laboratories, 121
- 77 • CARE for calibration of laboratory data. 122

## 79 2. CARE for the profession 123

80 The installation of the EC4 Register of European 124  
81 Clinical Chemists is a large step forward to the attain- 125  
82 ment of the first level, Recognition of Equivalence of 126  
83 Standards of the profession. Individual medical labo- 127  
84 ratory specialists should and do apply for registration. 128  
85 In most EU countries, national registers of medical la- 129  
86 boratory specialists exist. In some countries several 130  
87 registers exist, depending on the academic education of 131  
88 the medical laboratory specialist. Colleagues from all 132  
89 relevant academic background, scientific as well as 133

90 medicine, pharmacy, veterinary and others, may and do 91  
92 apply. The EC4 Register is based on the Recognition of 93  
94 Equivalence of Standards to national registers by the 95  
96 EC4 Registration Committee and the EC4 Board. 97

98 The free exchange of goods and services and the 99  
99 freedom of movement within the European Union 100  
100 includes the free exchange of professionals between 101  
101 all member states. To make sure that the competence of 102  
102 all clinical chemists fulfils a common minimum stand- 103  
103 ard the European Communities Confederation of Clin- 104  
104 ical Chemistry (EC4) agreed to promote recognition of 105  
105 the profession by establishing a European register. The 106  
106 operation of the register is based on the European 107  
107 Syllabus [1] defining the necessary items of postgrad- 108  
108 uate education, and the Guide to the register [2,3], 109  
109 giving the basic education and the rules for entering the 110  
110 register. 111

112 To set up the register, EC4 installed a register 113  
113 commission (EC4RC) in 1997. Each society was in- 114  
114 vited to send one delegate to EC4RC. A board was 115  
115 elected and the structures for the operation of the re- 116  
116 gister were developed. National register committees 117  
117 are keeping the national registers and are asked to keep 118  
118 EC4RC well informed about the national education 119  
119 and training structure. Applicants may appeal against 120  
120 EC4RC decisions to the EC4 Committee of Appeal. 121

122 Following the guide to the register, EC4RC ac- 123  
123 knowledges the national registers if they meet the 124  
124 requirements of the Syllabus. Individual applications 125  
125 have to be voted by both NCCRCs and EC4RC. If there 126  
126 is no national post graduate education and no national 127  
127 register organised, EC4RC considers application on an 128  
128 individual basis. The register was opened in 1998 [4]. 129

130 The EC4 European Syllabus for Postgraduate Train- 131  
131 ing forms the basis for the European Register. It is not 132  
132 a training guide as such, but must be seen as an in- 133  
133 dication of the level of requirements in postgraduate 134  
134 training and the content of national programs needed to 135  
135 obtain appropriate knowledge and experience. It is a 136  
136 common minimal program approved by all EU soci- 137  
137 eties of clinical chemistry and leaves undisturbed the 138  
138 different structures of medical laboratories as devel- 139  
139 oped in their national environments. Some of its core 140  
140 elements are: knowledge in clinical chemistry, hemato- 141  
141 logy, bloodbanking, immunology, etc.; knowledge on 142  
142 pre-analytical aspects including consultancy regarding 143  
143 requesting; analysis and methodological evaluation of 144  
144 analytical findings and interpretation of data; clinical 145

138 training; research and development; laboratory man-  
139 agement and quality assurance. Such a syllabus is the  
140 reflection of a profession of which the contents are  
141 changing continuously. Therefore, it needs to be up-  
142 dated regularly. A second version has been published  
143 recently [1]. The Syllabus is the basis of clinical che-  
144 mistry in Europe.

145 The context of clinical chemistry differs for differ-  
146 ent countries (Table 1). In many countries, clinical  
147 chemistry is practiced on a polyvalent base in contrast  
148 to the much more narrow practicing in the US. The  
149 polyvalency is covered by the Syllabus.

150 To enter the training a university degree is de-  
151 manded. In the European Union, the university educa-  
152 tion for MDs averages to 5–6 years, range 4–7 years.  
153 For PhDs, the average university education (biology,  
154 biochemistry, chemistry or pharmacy) is 5.5 years,  
155 range 4–7 years. Postgraduate training for MDs and  
156 PhDs is 5–7 years on the average, range 4–8. The mi-  
157 nimum standard for the European Register is at present  
158 8 years of study after entering the university (BAC + 8).

159 Official legal national registers for MDs exist in all  
160 EU countries except for Germany, Ireland and Italy. For  
161 PhDs legal national registers do not exist in Austria,  
162 Denmark, Germany, Greece, Ireland, Italy and The Ne-  
163 therlands. In several countries, voluntary society linked  
164 registers exists.

165 The EC4 Registration Commission keeps the Euro-  
166 pean Register. Members are representatives of the Na-

tional Clinical Chemistry Register Committees. The 167  
EC4RC is responsible for the European Syllabus. On 168  
the basis of the Syllabus, it grants Equivalence of Stan- 169  
dards to national training schemes. Equivalence of 170  
standards has been granted to national training schemes 171  
of 13 European Union countries. The EC4RC consi- 172  
ders and decides on individual applications that are not 173  
straightforwardly accepted by the EC4RC board. 174

### 2.1. Operation of the register 175

The guide to the Register [3] describes the oper- 177  
ation of it. Applicants send in the application form 178  
plus their CV to the NCCRC. The NCCRC forwards 179  
these to the EC4RC president including a recommen- 180  
dation. The EC4RC president judges the application. 181  
If the national register has been granted Equivalence 182  
of Standards, if the NCCRC recommendation is 183  
positive and if the CV proves that the applicant is 184  
still professionally active, the EC4RC board automati- 185  
cally accepts the application. Registration in the EC4 186  
Register leads to the title European Clinical Chemist 187  
for the applicant. If the recommendation of an 188  
NCCRC having Equivalence of Standards is negative 189  
the application will be discussed by the EC4RC and 190  
be rejected. If the application comes from a country of 191  
which the NCCRC has not been granted Equivalence 192  
of Standards, the application will be considered by the 193  
EC4RC. 194

t1.1 Table 1

t1.2 Content of clinical chemistry in the European Union countries

t1.3		Clinical (bio) chemistry			Microbiology	Blood
t1.4		Clinical chemistry	Hematology	Immunology		banking
t1.5	Austria	yes	yes	yes	yes	yes
t1.6	Belgium	yes	yes	yes	yes	yes
t1.7	Denmark	yes	yes	<b>(no)</b>	<b>no</b>	<b>no</b>
t1.8	Finland	yes	yes	yes	<b>no</b>	(yes)
t1.9	France	yes	yes	yes	yes	yes
t1.10	Germany	yes	yes	yes	<b>no</b>	<b>no</b>
t1.11	Greece	yes	yes	yes	yes	yes
t1.12	Ireland	yes	<b>no</b>	<b>no</b>	<b>no</b>	<b>no</b>
t1.13	Italy	yes	yes	yes	yes	<b>no</b>
t1.14	Luxemburg	yes	yes	yes	yes	yes
t1.15	Netherlands	yes	yes	yes	<b>(no)</b>	yes
t1.16	Portugal	yes	yes	yes	yes	<b>no</b>
t1.17	Spain	yes	yes	yes	yes	yes
t1.18	Sweden	yes	yes	yes	<b>no</b>	<b>no</b>
t1.19	United Kingdom	yes	<b>no</b>	<b>no</b>	<b>no</b>	<b>no</b>

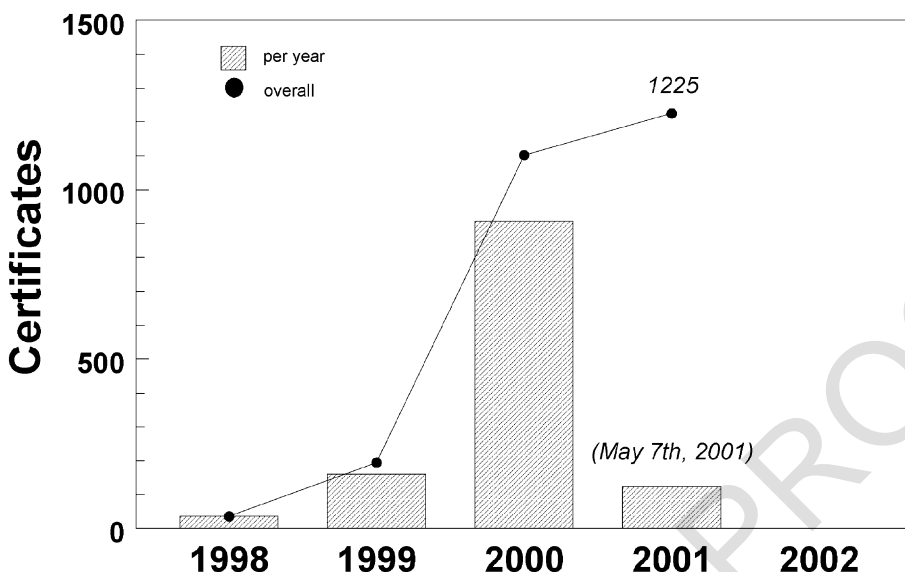


Fig. 1. Number of EC4 European Clinical Chemist certificates per year and cumulative. After the advise of the European Commission to the Ordre de Pharmaciens in France, the number of French biologistes cliniques applicants increased greatly.

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

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

quickly and exponentially (Fig. 2) after the recommen-  
 dation 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

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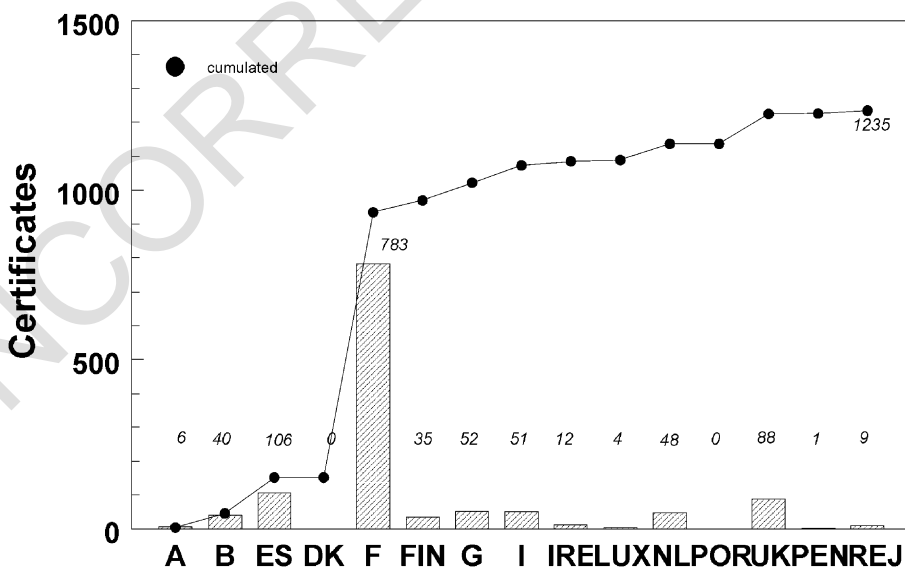


Fig. 2. Number of certificates per country.

207 regarding Professional Recognition. EC4 is active to  
208 convince the Commission of the necessity to recognise  
209 a system of Common Platforms governed by the pro-  
210 fessions under the supervision of a General European  
211 Board of National Coordinators. The EC4 Register and  
212 the FEANI Register of European Engineers are the first  
213 examples of such Common Platforms.

## 214 215 2.2. Number of consultants

216 EC4 is working on a guideline for the desirable  
217 number of consultants. A working group is presently  
218 making an inventory of the existing situation regarding  
219 the number of consultants practicing in medical labo-  
220 ratories in the EU. The working group also makes an  
221 inventory of existing national guidelines and legisla-  
222 tion.

## 223 3. CARE for laboratories

224 EC4 coordinates activities for recognition on the  
225 basis of accreditation standards for medical laborato-  
226 ries. Several publications [6–8] have contributed to the  
227 development of the ISO 15189 draft International  
228 Standard related to quality systems and competence  
229 of medical laboratories. The EC4 Essential Criteria are  
230 widely used as practical guidelines for implementation  
231 of quality systems in medical laboratories. A Model  
232 Quality Manual is a further tool to help individual la-  
233 boratories to set up their quality system [9,10]. EC4  
234 coordinates and promotes the voice of professionals in  
235 the relevant CEN and ISO committees and working  
236 groups, to improve the influence of the profession on  
237 the development of standards, that influence directly  
238 our work.

## 239 4. CARE for calibration of data

240 EC4 stimulates developments for harmonisation of  
241 laboratory data. The Calibration 2000 project of The  
242 Netherlands is such a project [11]. The materials de-  
243 veloped in this project are commutable with patient  
244 materials and should be tested on an international base  
245 to investigate their potency as international secondary  
246 reference materials. In the Reference Systems [12]  
247 needed for the implementation of the In Vitro Diag-

248 nostics directive of the European Union, there is a need  
249 for commutable secondary reference materials. Such  
250 materials should be available for industry as well as  
251 profession. It is the responsibility of the professional to  
252 estimate within and between laboratory variations and  
253 to decide whether correction for observed bias is  
254 needed in a particular laboratory situation. For such  
255 corrections, commutable secondary reference materials  
256 are necessary.

## 257 5. Conclusions

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

271 The authorities and the public demand demonstra-  
272 ble quality. This is and will be particularly important in  
273 health care. Laboratory medicine has evolved into a  
274 core discipline in diagnosis. It is essential that labo-  
275 ratory information is provided with the highest qua-  
276 lity. Such quality requires appropriately educated and  
277 trained consultants as well as adequately functioning  
278 laboratories. EC4 has published essential criteria for  
279 quality systems of medical laboratories, which formed  
280 the basis for an ISO draft international standard regard-  
281 ing quality and competence of medical laboratories.

282 There is a need for commutable secondary reference  
283 materials to harmonize laboratory data. Continuity of  
284 laboratory data makes the absence of bias and stability  
285 in time increasingly important. Also the developments  
286 in health care in which patients are treated in health care  
287 chains, often involving primary, secondary and tertiary  
288 institutes, many physicians and several laboratories,  
289 requires harmonization of laboratory data between  
290 laboratories. EC4 stimulates projects like the Calibra-  
291 tion 2000 project in the Netherlands which focus on  
292 this topic.

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