



European Communities Confederation of
Clinical Chemistry and Laboratory Medicine

Self and Co-regulation for Science and Pharmacy Specialists in Clinical Chemistry and Laboratory Medicine

Position paper

The "Directive 2005/36/EC of the European Parliament and of the Council on the Recognition of Professional Qualifications" was adopted by the Council in June 6th 2005 and published in the Official Journal of the European Union 2005 volume 48 September 30th; L 255: 22. The directive provides for automatic recognition in most countries of the profession of Specialist in Clinical Chemistry and Laboratory Medicine for medicine educated specialists in the specialties Clinical Biology and Biological Chemistry. However, although the same specialty is practised also by science and pharmacy educated specialists, these professionals do not enjoy automatic recognition. The European Commission has opened the possibility of self and co-regulation of such professions. The European Communities Confederation of Clinical Chemistry and Laboratory Medicine (EC4) presents its system of self regulation for science and pharmacy educated specialists in clinical chemistry and laboratory medicine. Acceptance for co-regulation by the European Commission should provide a simple system for automatic recognition of qualifications of the profession between EU countries.

The profession

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 businesses' of health care. Medical laboratories play an essential role in this. The broad and exponentially growing 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 is of the utmost importance, since it directly contributes to patient safety and the measurability for the consumer. The profession performs in one of the most innovative fields of medicine, for instance the introduction of tumour markers, nucleic acid testing (DNA), cardiac markers and immunochemistry techniques in routine (non-research) laboratories is having an enormous impact on diagnosis and therapy.

The profession of specialist in Clinical Chemistry and Laboratory Medicine is practised in Europe at equal level of responsibility by persons educated in medicine, pharmacy, or science, which includes biology, biochemistry and chemistry. Qualified specialists have substantial commonality in their post-academic training and qualifications. For medically

educated specialists the profession enjoys automatic recognition in two specialties in the directive, 'Clinical Biology' and 'Biological Chemistry'. Science and pharmacy educated specialists, covered by the general system in the Directive, do not enjoy automatic recognition.

In the European Union of 27 countries there are about 30.000 specialists in clinical chemistry and laboratory medicine. The annual turnover is twenty billion Euro ($\text{€ } 20 \cdot 10^9$).

Need for Self and Co-regulation

There is no automatic recognition for the science and pharmacy educated specialists. Presently the level of training of migrating professionals is often unclear and the reason for refusal. In several cases EC4 has been called upon for information regarding the level of training. Demonstration by the candidate of being registered in the EC4 European Register has lead to acceptance with or without compensation measures. Also not being at the level of the European register has been an argument for refusal. The European Register serves on an ad hoc basis as a co-regulation system. The competence of the migrating professional is essential, since the nature of the profession is directly related with patient safety and this should be measurable for the consumer. Therefore there is a need for a formal co-regulation system.

Examples of cases are given in the annex to the establishing document.

EC4 presents the following documents for self and co-regulation:

- An inventory of the present situation including a comparison between the situations in the 12 Member States that have regulated the profession.
- A document defining the level and content of training and a system of compensating measures

The documents describe the situation in 26 of the 27 European Union Countries. For Malta only limited data are available as yet.

Who is EC4?

EC4 is the EU organisation for Clinical Chemistry and Laboratory Medicine. It is the EU branch of the broad European Federation of Clinical Chemistry and Laboratory Medicine (EFCC) and the world wide International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). It is an organisation governed by the membership of the IFCC linked national organisations of clinical chemistry and laboratory medicine of the EU countries. In each country only one organisation exists that is member of IFCC and of EC4. Members of the national societies are pharmacy, science as well as medically educated specialists. The national organisations are: Austria (Österreichische Gesellschaft für Klinische Chemie), Belgium (Société Belge de Chimie Clinique/ Belgische vereniging voor Klinische Chemie), Bulgaria (Bulgarian Society of Clinical Laboratory), Cyprus (Association of Clinical Laboratory Directors, Biomedical and Clinical Laboratory Scientists), Czech Republic (České společnosti klinické biochemie), Denmark (Danish Society for Clinical Chemistry), Estonia (Estonian Society of Laboratory Medicine), Finland (Suomen Kliinisen Kemian Yhdistys), France (Société Française de Biologie Clinique), Germany (Deutsche Vereinte Gesellschaft für Klinische Chemie und Laboratoriumsmedizin), Greece (Ελληνικής Εταιρίας Κλινικής Χημείας - Κλινικής Βιοχημείας), Hungary (Magyar Laboratóriumi Diagnosztikai Társaság), Ireland (Association of Clinical Biochemists in Ireland), Italy (Società Italiana di Biochimica Clinica e Biologia Molecolare Clinica), Latvia (Latvian Society of Laboratory Specialists), Lithuania (Lithuanian Society of

Laboratory Medicine), Luxembourg (Société Luxembourgeoise de Biologie Clinique), Malta, Netherlands (Nederlandse Vereniging voor Klinische Chemie en Laboratoriumgeneeskunde), Poland (Polskie Towarzystwo Diagnostyki Laboratoryjnej), Portugal (Sociedade Portuguesa De Química Clínica), Romania (Romanian Society of Laboratory Medicine), Slovakia (Slovenská spoločnosť klinickej biochémie), Slovenia (Slovensko združenje za klinično kemijo), Spain (Sociedad Española de Bioquímica Clínica y Patología Molecular), Sweden (Svensk Förening för Klinisk kemi), United Kingdom (Association for Clinical Biochemistry). In some countries as well as the IFCC related societies, organisations specifically for medical professionals exist. The medical professionals are in most cases member of both societies.

EC4 represents about 30.000 specialists. It holds the European Register of Specialists in Clinical Chemistry and Laboratory Medicine, which presently helps for advice on defining the level of training and compensating measures.

EC4 is active in continuous quality improvement in laboratory medicine. It is important that laboratory medicine is practised at an adequate level throughout the European Union.

EC4 plays a central role in the co-ordination of reaching equivalence of standards in laboratory medicine across the European Union. A reference list of articles and guidance documents published by EC4 is attached to this Position Paper and included in the self and co-regulation documentation.

EC4 is in close contact with representatives of the national societies for clinical chemistry and laboratory medicine. The contact with the national authorities and registers are via the national representatives of the member societies. The representatives meet twice a year.

Co-regulation of the profession of (science and pharmacy) Specialists in Clinical Chemistry and Laboratory Medicine will facilitate migration of specialists and at the same time provide transparency and assurance of quality to the consumer, the governmental authorities and the profession itself. EC4 is prepared to offer further information and any assistance needed for establishment and implementation of the co-regulation.

Dr. M. Hallworth, President

Dr. R.T.P. Jansen, Past-President

Dr. S. Zérah, Chair Registration Commission

List of publications

1. Zerah S, McMurray J, Bousquet B, Baum H, Beastall GH e.a. (EC4 Register Commission). EC4 European Syllabus for Post-Graduate Training in Clinical Chemistry and Laboratory Medicine: version 3 – 2005. Clin Chem Lab Med 2006; 44(1):110–120.
2. Beastall GH, Kenny D, Laitinen P and Kate ten J. A guide to defining the competence required of a consultant in clinical chemistry and laboratory medicine. Clin Chem Lab Med 2005; 43(6):654–659.
3. Sanders G, Opp M, McMurray J, Koeller U, Blaton V e.a. The European Register for Specialists in Clinical Chemistry and Laboratory Medicine: Code of Conduct. Clin Chem Lab Med 2004; 42(5):563–565.
4. Gurr E, Köller U, Blaton B, Lund E, Harmoinen A e.a. (European Communities Confederation of Clinical Chemistry and Laboratory Medicine (EC4), EC4 Register Commission). The European Register for Specialists in Clinical Chemistry and Laboratory Medicine: Guide to the Register Version 2-2003 and Procedure for Re-registration. Clin Chem Lab Med 2003; 41(2):238–247.
5. Jansen RTP. The EC4 register of European clinical chemists and EC4 activities. Clinica Chimica Acta 2002; 319: 143-148
6. Sanders GT, Beastall GH, Kohse KP, Zerah S, Jansen R, Köller U, Blaton V, Lund E, Parviainen M, Charret J, Gurr E, Nicholou H, Kenny D, Pazzagli M, Opp M, Willems H, Carmo Martins M do, Queraltó JM, Landin B, Yu A and McMurray J. On the practice and training of clinical chemistry in the European Union. Clin Chem Lab Med 2002; 40(2):196–204 © 2002 by Walter de Gruyter · Berlin · New York
7. Jansen RTP, Blaton V, Burnett D, Huisman W, Queraltó JM, Zerah S, Allmann B. European Confederation of Clinical Chemistry: Essential criteria for quality systems of medical laboratories. European Journal of Clinical Chemistry and Clinical Biochemistry 1997;35:121-132
8. Jansen RTP, Balton V, Burnett D, Huisman W, Queraltó JM, Zerah S, Allman B. Additional Essential Criteria for Quality Systems of Medical Laboratories. Clin.Chem.Lab.Med. 1998; 36: 249-252.
9. Jansen Rob , Schumann Gerhard, Baadenhuijsen Henk, Franck Paul, Franzini Carlo, Kruse Rolf, Kuypers Aldy, Weykamp Cas, Panteghini Mauro. Trueness verification and traceability assessment of results from commercial systems for measurement of six enzyme activities in serum. An international study in the EC4 framework of the Calibration 2000 project. Clinica Chimica Acta 2006; 368: 160-167.