Welcome to this edition of EC4 News - a publication which aims to keep you informed of the work of EC4 and other developments in Clinical Chemistry and Laboratory Medicine in the European Union.

What is EC4?

EC4 is the European Communities Confederation of Clinical Chemistry and Laboratory Medicine - formed in 1993 to co-ordinate the activities of national clinical chemistry societies affiliated to IFCC in the European Union (EU) and to promote harmonisation of practice and scientific quality across EU countries. EC4 is an autonomous group, but works closely with the Federation of European Societies of Clinical Chemistry and Laboratory Medicine (FESCC), the European regional organisation of IFCC.

EC4 Operation

EC4 has an Executive Board and various active Working Groups - the elected Board members for 2005-8 are:

President: Mike Hallworth (UK)
Secretary: Rita Horvath (HU)
Treasurer: Peter Schuff-Werner (DE)
Member at Large: Aimo Harmoinen (FI)
Member at Large: Mario Pazzagli (IT)
Member at Large: Pika Mesko-Brguljan (SL)

and the working group chairs are:

Register: Simone Zerah (FR)
Accreditation: Wim Huisman (NL)
ISO/CEN: Des Kenny (IR)
Profession: Rob Jansen (NL)
Guidelines: Paivi Laitinen (FI)
QA in molecular biology: M Pazzagli (IT)
Creatinine standardization: J Delanghe (BE)

If you have any questions about EC4 or its activities please email the Secretary (horvath@clab.szote.u-szeged.hu).

Developments in Accreditation and ISO/EN/15189

The only acceptable standard for accreditation of medical laboratories is ISO/EN/15189: Medical laboratories - Particular requirements for quality and competence, which was published in 2002 and is now the preferred standard for accrediting Medical laboratories all over the world, with a few exceptions remaining in Europe. An amendment to the Standards was recently approved with no votes against, and version 2 (with very few modifications) will be published soon. This standard includes all relevant steps: pre-analytical, analytical and post-analytical and overall quality management. It stresses the consultant function of the laboratory, ethical aspects, turn-around
time, and the relationship with requesting physicians and patients. It sees medical laboratories in the context of the whole health system, and insists on the competence of the Director and adequate standards across the whole service.

Members of the EC4 working group (WG) on ISO/EN/15189 were and are directly involved in the formulation and implementation of this standard to ensure proper quality of care for the patient. Two additional documents have been published subsequently and are expected to be republished as annexes to ISO/EN/15189:

ISO 15190: 2003 Medical laboratories. Requirements for safety and
ISO 22870: 2006 point of care testing (POCT): requirements for quality and competence

Harmonisation of accreditation is a major current area of activity. An information-gathering questionnaire was distributed by the EC4 Accreditation WG in March 2005, with the following results:

1. Accreditation has just begun in the majority of EU countries. Only in Sweden, UK and The Netherlands are the majority of clinical chemistry laboratories currently accredited.

2. In some countries, accreditation for medical laboratories was originally done according to ISO 17025, but it is gradually changing to ISO/EN/15189. The ISO/EN/15189 standard is now accepted by nearly all Accreditation Bodies.

3. Medical laboratory professionals are trained as assessors and play a major role in the assessment process.

4. Co-operation with the accreditation bodies of the EA (European Cooperation of Accreditation) is the preferred way towards mutual lateral agreement: (the acceptance of an accreditation in another country).

5. EC4 is involved in the EA committee dealing with accreditation in the health care sector. It is very important that more professionals are involved in this process, to reach an acceptable result.

6. Accreditation by individual tests makes no sense for laboratory professionals, but unfortunately is the approach taken by many EA bodies.

7. Accreditation was originally introduced by CPA (UK) and CCKL (Netherlands) for a whole service, dealing with the broad scope of laboratory testing, but accreditation by test is preferred by the majority of EA bodies. EC4 has produced a position paper on this issue, and it is being discussed in the WG and with the EA committee.

8. The frequency of assessment visits is an important factor in ensuring that laboratory professionals are part of the assessment team.

9. The WG has an important role in harmonisation and has worked on requirements for validation and the retention time for documents.

The EC4 Register

The EC4 Register of European Specialists in Clinical Chemistry and Laboratory Medicine was set up in 1998 and opened to applicants in 1999. There are now 1800 registrants in 15 countries, who are entitled to use the designation EurClinChem. One of the main aims of the register is to establish a framework of mutual recognition of qualifications to assist free movement within the EU. The register is organised by the EC4 Register Commission on which there is a National Representative from each of the EU countries with 23 of the 25 countries currently represented (all except Malta and Cyprus). The register is open to specialists from medical, science or pharmacy backgrounds who can show that they meet the education and training standards set by EC4. To recognise that
there are differences both in the educational and training systems and in the practice of clinical chemistry and laboratory medicine between the countries, the first step in opening the register is for each country to show that it meets EC4 standards and complies with the EC4 Syllabus (1). This is done using an Equivalence of Standards declaration. Once the Equivalence of Standards has been approved by the Register Commission the register is opened to that country. To date, Equivalence of Standards status has been granted to 18 countries including four of those which joined the EU in 2004. All applications must be approved by the relevant National Clinical Chemistry Register Committee (NCCRC) before being submitted to the EC4 Register Commission.

EC4 Registration is valid for five years after which time individuals must apply to re-register via a process similar to first registration; they must be participating in continuing professional development and agree to abide by the EC4 Code of Conduct (2). Those who registered in 1999 and 2000 have recently been invited to apply for re-registration.

Application for registration and re-registration is done on-line via the EC4 website (www.ec-4.org) with appropriate documents being sent to the NCCRC. Registrants can also access and update their personal details on-line using a secure password.

The Register as a Common Platform

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). In the directive the profession of Specialist in Clinical Chemistry and Laboratory Medicine is defined as regulated for medically trained specialists in most countries (either as Clinical Biology or Biological Chemistry), but there is no regulation for pharmacy or science-trained specialists. The directive introduces a system of Common Platforms. A Common Platform should provide a simple and self-regulating system for mutual recognition of qualifications in a particular profession between EU countries. In the advice of the European Economic and Social Committee on the draft Directive, the EC4 Register was named as one of three examples of common platforms. EC4 is in discussion with the European Commission to install a common platform for our profession.

The EC4 Register provides a platform for a simple and self-regulating system for mutual recognition of individual professionals, specialists in clinical chemistry and laboratory medicine. The profession of specialist in Clinical Chemistry and Laboratory Medicine is practised in Europe at an equal level of responsibility by persons educated in medicine, pharmacy, or science (including biology, biochemistry and chemistry). Qualified specialists have substantial commonality in their post-academic training and qualifications. Specialists from all educational backgrounds register in the EC4 Register.

The essential role of medical laboratories in diagnosis and therapy and the broad
The best starting point for any enquiry about Clinical Chemistry and Laboratory Medicine in the EU, or to find out more information about the issues above, is the EC4 website –

This edition of EC4 News was prepared by Mike Hallworth, Wim Huisman, Rob Jansen, Janet McMurray and Simone Zerah as President and Working Group officers.