

## PROFILE

# The European Communities Confederation of Clinical Chemistry and Laboratory Medicine (EC4)

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### Introduction

Laboratory medicine may be defined as the use of laboratory methods to diagnose and monitor disease. Laboratory medicine covers a range of disciplines, including Clinical Chemistry (based on chemical analysis of blood and other body fluids), Haematology (the study of blood cells and blood disorders), Microbiology (the study of bacteria, viruses and infectious diseases) and Histopathology (the study of tissues and organs). All areas of laboratory medicine have a strong emphasis on quality assurance, and specialists in laboratory medicine have often led the way in improving quality in other areas of medicine.

The freedom of movement of people and goods across national boundaries is an essential principle of the European Union (EU). In health care, it is important that patients are confident that professional practice reaches common standards across the EU, and that they can expect satisfactory standards of practice whichever country they are in.

The European Communities Confederation of Clinical Chemistry (EC4) was formed in 1993 to promote harmonisation of practice and scientific quality in clinical chemistry across EU countries and to co-ordinate the activities of national clinical chemistry societies. EC4 does not have

individual members; its members are national societies in EU countries. Currently, 23 countries out of the 25 EU members have national clinical chemistry societies, all of which are members of EC4. EC4 has a specific remit for the European Union, but is affiliated to larger organisations with a wider geographical remit – the Federation of European Societies of Clinical Chemistry and Laboratory Medicine (FESCC) and the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). As if EC4's name was not already long enough, in 2002 it was changed to the European Communities Confederation of Clinical Chemistry and Laboratory Medicine, to be consistent with the renaming of FESCC and IFCC. Fortunately, everyone still calls it EC4, otherwise we would never get anything done – and, as you'll see, we do quite a lot!

### Structure

EC4 is an autonomous organisation, constituted as a Foundation under Dutch law. Of the 25 EU nations 23 (all except Malta and Cyprus) have representatives on the General Assembly of EC4, which meets once a year. The activities of EC4 are directed by an elected Executive Board. The Executive Board members for 2005–2008 are:

|            |                     |         |
|------------|---------------------|---------|
| President: | Mike Hallworth      | UK      |
| Secretary: | Andrea Horvath      | Hungary |
| Treasurer: | Peter Schuff-Werner | Germany |

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| Member: | Mario Pazzagli      | Italy    |
| Member: | Aimo Harmoinen      | Finland  |
| Member: | Pika Mesko-Brguljan | Slovenia |

Various task-specific Working Groups report to the Executive Board.

## Aims and Activities

In European health care, patients move frequently between primary health care institutes (local practitioners) and secondary or tertiary institutions. This process may involve many health care professionals, and may include several different clinical laboratories. Laboratory medicine has a vital role in diagnosis and monitoring in modern health systems. It has been estimated that 70% of medical decisions depend on laboratory data, and it is vital to ensure acceptable quality of both professionals and laboratories, and commutability of laboratory data within and between laboratories.

EC4 seeks to foster harmonisation, co-operation and improved quality in laboratory medicine across the EU. The goals of EC4 are:

- Co-operation for the advancement of the science of clinical chemistry and laboratory medicine, within the EU in particular and Europe in general.
- Co-operation to attain recognition of professional qualifications at European level, to enable free movement of professionals within the EU.
- Co-ordination and recognition of equivalence of standards of accreditation and quality systems in medical laboratories.
- Co-operation on a common professional view in International Organization for Standardization (ISO) and European Committee for Standardization (CEN) deliberations related to laboratory medicine.
- Formulating and collating European guidelines on the laboratory investigation of disease.
- Co-operation in evaluating the effects of EU Directives on professional practice and on laboratories and laboratory data.

- Co-operation to enhance public understanding of the science of laboratory medicine and the significance of laboratory data.

It addresses these goals in three main ways:

- (a) Standards for professionals: the European Register.
- (b) Standards for laboratory quality: accreditation, ISO/CEN standardisation and the EC4 Quality Manual.
- (c) Standardisation of laboratory data: desirable analytical performance standards, common calibration for laboratory data and guidance on effective use of laboratories.

This profile will describe the three areas of activity briefly, but more details (including the full EC4 Strategic Plan for 2005–2008) are available on the EC4 website, <http://www.ec-4.org>.

### (a) *Standards for professionals: the European Register*

EC4 operates and promotes the Register of European Specialists in Clinical Chemistry and Laboratory Medicine [1], which was established in 1997 and now numbers over 1700 registered professionals across the EU. The Register is based on a common European Syllabus [2] defining the standards and training required for entry to the register. Registration is open to both medically and scientifically qualified professionals, provided the training criteria are met, and those admitted to the register are entitled to use the title European Specialist in Clinical Chemistry and Laboratory Medicine and the letters EurClinChem, which certify a common standard of professional training.

It is expected that the Register will be recognised as a Common Platform under the proposed EU Draft Directive on Recognition of Professional Qualifications, which will give formal legal status to a successful informal arrangement.

EC4 also has recently completed guidelines on essential criteria for the competence of heads of clinical chemistry laboratories and senior

consultants [3], including interpretative skills and the efficient and effective use of laboratory tests.

(b) *Standards for laboratory quality: accreditation, ISO/CEN standardisation and the EC4 Quality Manual*

EC4 has two very active working groups on Accreditation of Laboratories and ISO/CEN standardisation, which work in close harmony and act as the voice of the profession on relevant CEN and ISO committees and working groups. The Chair of the EC4 ISO working group is also the current chair of ISO TC 212 WG 1, and several EC4 publications [4–6] contributed to the ISO 15189 standard which defines requirements for quality and competence of medical laboratories. Work continues on annexes to ISO 15189, notably on point-of-care testing and safety in laboratories. EC4 also co-ordinates professional activities towards the European Cooperation for Accreditation (EA) and national accrediting organisations, with the aim of establishing ISO 15189 as the relevant standard for accreditation of European medical laboratories. The EC4 Essential Criteria [4, 5] are widely used as practical guidelines for implementation of quality systems in medical laboratories, and the EC4 Model Quality Manual (7) is a further tool to assist laboratories in establishing a quality system.

(c) *Standardisation of laboratory data and guidelines on investigation*

The EC4 EQUAL project began work in 2004 and aims to develop a European quality assessment scheme and training courses on Nucleic Acid Testing in Clinical Laboratories. The project has attracted a substantial grant from the European Commission and will report in 2006–2007.

A joint FESCC/EC4/European Diagnostics Manufacturers Association (EDMA) working group on desirable analytical performance is seeking to define essential criteria for clinically relevant analytical requirements, based on published work and related to the EU directive on *in vitro* diagnostics.

Also, EC4 is active in stimulating developments towards harmonisation of numerical

laboratory data through the use of common calibrants (commutable secondary reference materials). The Calibration 2000 project in the Netherlands is such a project [8, 9], and the lessons learned will be studied for potential pan-European application.

Guidelines for the investigation of certain disease states, based on evidence published in the literature, are also being produced, with the first one (on the investigation of thrombophilia) published in March 2003 [10].

## Conclusion

EC4 is the organisation within the European Union for promotion and harmonisation of clinical chemistry and laboratory medicine. It is a productive organisation, with a range of activities and influential publications on professional practice, analytical quality and quality management. Further details may be obtained from the EC4 website, or by contacting the author directly.

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