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Harmonisation of Lab Medicine Across Europe



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Under EU Directive 2013/55/EU, harmonisation of lab medicine across Europe could lead to an exchange and spread of skills and expertise and better patient outcomes.

In the last few years there has been a continuous growth in the awareness of the importance of harmonisation of professional qualifications across the European Union (EU) in all medical fields. EU Directive 2013/55/EU acts as a passport for personnel seeking to work in other EU states for professions that can work to the Common Training Network.

One area where harmonisation is critical is laboratory medicine; harmonisation is a fundamental aspect of quality and its main goal is to provide a better patient outcome producing comparable laboratory information regardless of the origins of the data.

With lab medicine harmonisation firmly on the EU agenda, it featured as the topic of the opening session at EuroMedLab held in Athens in June and attended by HealthManagement.org. Speakers at the session were Wim Huisman, previous Head of the Clinical Chemistry and Haematology at Medical Centre Hoagland in Leidschendam, Ana-Maria Simundic, Professor in the Medical Department of Medical Biochemistry at Zagreb University, and Elizabeth Topic, Professor of Medical Biochemistry at the Faculty of Pharmacy and Biochemistry at the University of Zagreb and Chair of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM), Gilbert Wieringa.

Several key points came out of the EuroMedLab lab medicine harmonisation session.

Snapshot Overview

Although the focus is mainly on the standardisation of measurement procedures, the depth of harmonisation goes beyond method and analytical results: it includes all other aspects of laboratory testing (preanalytical, analytical, and post analytical phase). It embraces various aspects of the profession: from laboratory accreditation to professional development, to the recognition of laboratory medicine specialists in Europe. Freedom of movement for workers, recognition of vocational training qualifications, diplomas and professional qualifications are fundamental to the Directive.

More widely, the Directive provides a framework on administrative cooperation, information systems, right of establishment and the single market.

Recognition of risks

If professionals are moving across the EU borders, it is essential to be able to make surrounding EU states aware that there may well be risks. Many professionals who go to work abroad are told they have to undergo an adaptation period including possible aptitude tests.

The receiving country needs assurance from the host country that there is a minimum level of knowledge and skills that can be demonstrated. This has been recognised by the EU for many years.

Roadblocks to Increasing Professional Mobility

Under EU Commission Directive 2013/55/EU, the Recognition of Professional Qualifications harmonisation would extend opportunities for specialists to practice in other EU countries without having "compensation measures" imposed on them.

This involves not having to deal with re-taking local professional exams which, in turn, could lead to a more effective distribution of skills and resources across the EU. EU Commission Directive 2013/55/EU provides a passport to professional migration across EU borders for professions that can work to a Common Training Framework. This allows various EU states to identify the essential knowledge, skills and competence needed to practice at a particular level. If a training framework is clearly defined, then it can potentially be adopted by another EU community that can essentially provide a professional passport to travel. This provides an enormous opportunity for specialists in lab medicine.

Language Barriers

There is an obvious potential roadblock to effective harmonisation; language.

If a professional wants to go and work in another country, then the destination language needs to be learnt. The problem of language precludes the possibility of sharing clinical and administrative documentation easily across Europe.



Analytical tests use different methods that may not have been 'harmonised' or which may have different units of reporting. Inevitably the assumption made by clinicians is that the different numbers can be compared but this has the dangerous potential for misinterpretation of results and adverse patient outcomes.

Action Needed

The importance of harmonising the recognition of professional qualifications ensures that laboratory medicine is practised to common standards, so that patient safety is protected across any EU country. Through an understanding of the risks to patients undergoing laboratory testing, standardised operating procedures can be developed to reduce laboratory error and improve patient safety.

What was evident at this EuroMedLab session was the need to achieve a uniform accreditation system in Europe, the importance of promoting the free movement across European borders of laboratory medicine specialists assuring that competencies are practiced at an equivalent high quality level. The time frame for implementation of the directive, however, is not firm. There is an opportunity through harmonisation to support individuals, support the community and, ultimately, raise the profile of lab medicine. It remains unclear how long the harmonisation process will take, though the key lab organisations are maintaining close contact with its leads at the EU Commission.

Key Points

- EU Directive 2013/55/EU freedom of movement for workers, recognition of vocational training qualifications, diplomas and professional qualifications are fundamental to the Directive.
- Harmonisation is firmly on the agenda of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM)
- There is a growth in awareness in the EU of the importance of harmonisation of professional qualifications
- Harmonisation in laboratory medicine is critical
- Harmonisation could lead to beneficial skills and resources distribution around EU
- Lab medicine harmonisation embraces all aspects of the profession

- Country receiving cross-border staff needs assurance that skills are up to par
- An EU training framework could provide a universal approach to training and qualifications issue
- Non-harmonised analytical tests could lead to misinterpretation

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