European Specialist in Laboratory Medicine: where are we now?

Wytze Oosterhuis (UEMS)

Laboratory Medicine

Two professional organisations in Europe:

1. EFLM

2. UEMS Section Laboratory Medicine/Medical Biopathology

The main objectives of the UEMS:

- to promote free movement of specialist doctors within the EU.

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Objectives UEMS:

Free movement

- mutual recognition
  - equivalence of standards
    - harmonization of training

EFLM-UEMS joint activities:

1. Joint congress
2. Working group on Guidelines
3. Study laboratory specialists in the EU

1. Joint EFLM-UEMSCongress:

2010 Lisbon
2012 Dubrovnik
2014 Liverpool
2016 Warsaw

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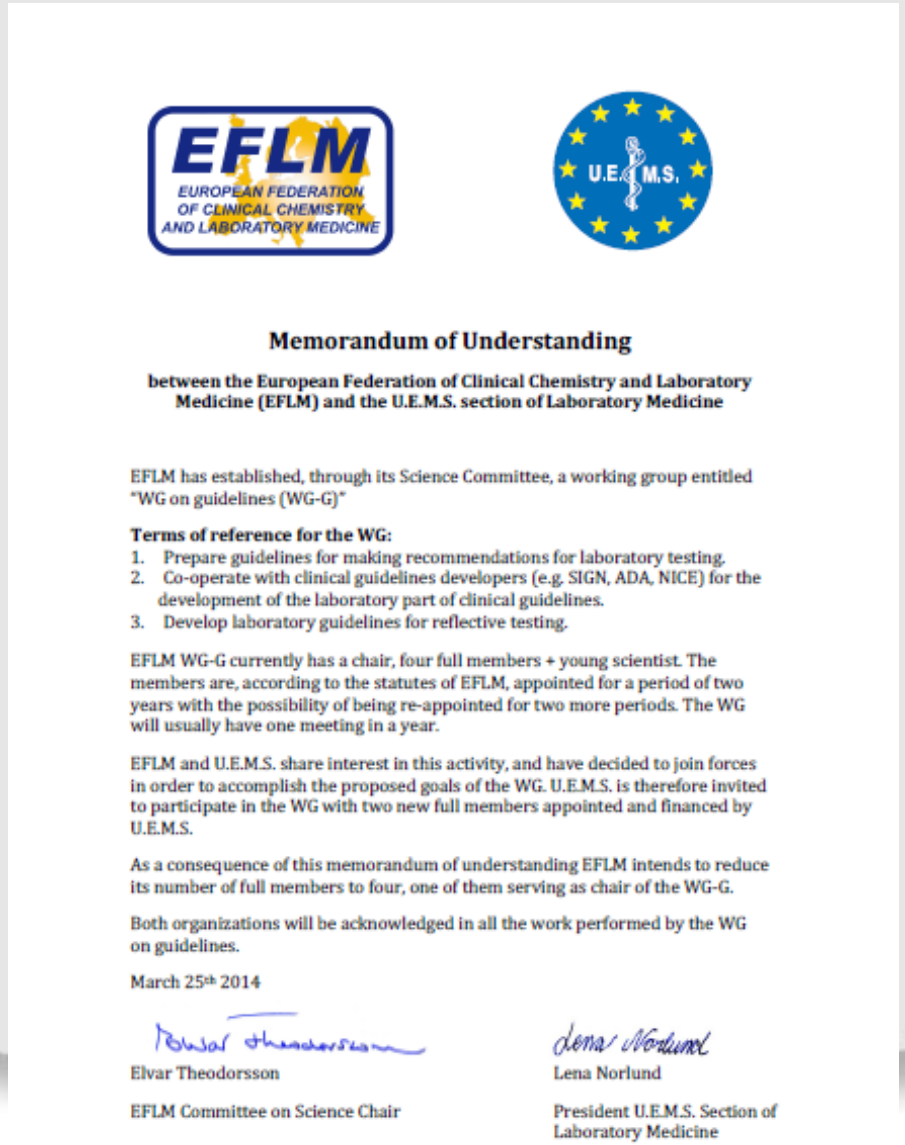
2. Joint EFLM-UEMS WG-guidelines 2014

Julian Barth (chair)



Memorandum of Understanding

between the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) and the U.E.M.S. section of Laboratory Medicine

EFLM has established, through its Science Committee, a working group entitled "WG on guidelines (WG-G)"

Terms of reference for the WG:

1. Prepare guidelines for making recommendations for laboratory testing.
2. Co-operate with clinical guidelines developers (e.g. SIGN, ADA, NICE) for the development of the laboratory part of clinical guidelines.
3. Develop laboratory guidelines for reflective testing.

EFLM WG-G currently has a chair, four full members + young scientist. The members are, according to the statutes of EFLM, appointed for a period of two years with the possibility of being re-appointed for two more periods. The WG will usually have one meeting in a year.

EFLM and U.E.M.S. share interest in this activity, and have decided to join forces in order to accomplish the proposed goals of the WG. U.E.M.S. is therefore invited to participate in the WG with two new full members appointed and financed by U.E.M.S.

As a consequence of this memorandum of understanding EFLM intends to reduce its number of full members to four, one of them serving as chair of the WG-G.

Both organizations will be acknowledged in all the work performed by the WG on guidelines.

March 25th 2014

Elvar Theodorsson

EFLM Committee on Science Chair

Lena Norlund

President U.E.M.S. Section of Laboratory Medicine

3. Study laboratory specialists in the EU

DE GRUYTER

Clin Chem Lab Med 2014; aop

Review

Wytze P. Oosterhuis* and Simone Zerah

Laboratory medicine in the European Union

Abstract: The profession of laboratory medicine differs between countries within the European Union (EU) in many respects. The objective of professional organizations of the promotion of mutual recognition of specialists within the EU is closely related to the free movement of people. This policy translates to equivalence of standards and harmonization of the training curriculum. The aim

Union (EU); harmonization; training; Union Européenne de Médecins Spécialistes (UEMS).

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Simone Zerah: European Federation of Clinical Chemistry and Laboratory Medicine (EFLM), Laboratoire Zerah-Taar-Pfeffer, Bagnolet, France

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Differences EFLM - UEMS

Europe (EU)

- Full members: 28 countries
- Candidates: 4 (Albania,Turkey, Montenegro, Macedonia, Serbia)

Europe (UEMS)

- Full members: 31 (incl. Norway, Switzerland, Iceland)
- Associated members: 4 (Armeria, Israel, Turkey)
- Observers: 2 (Libanon, Morocco, Georgia)

Europe (EFLM)

- Members: 40 countries

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Questionnaire UEMS-EFLM

- Sent to 28 EU countries (full members)
- UEMS and EFLM delegates

Questions:

- Numbers of laboratory specialists, labs
- Training, fields of interest
- Recognition
- Organizations
- Accreditation

Questionnaire

Questionnaire UEMS/EFCC

Introduction

This questionnaire concerns the field of clinical chemistry. This might be defined most easily as the profession responsible in your country for tests like sodium, creatinine etc. In some countries clinical chemistry might include fields like blood transfusion, microbiology etc. The name "clinical chemistry" might not be used in your country.

We tried to use objective definitions for specialties and specialists. In the most general way, any person with a medical training and a post-graduate specialization in this field is here referred to as "laboratory physician", any person with an academic training and additional post- graduate specialization is here referred to as "laboratory specialist". "Scientific" training means any academic training (including pharmacy) other than medicine. Any person with an academic training – with or without additional specialization - working in the laboratory is defined as "laboratory professional".

Please answer this questionnaire, even if not all answers to the questions are known. If you do not know the exact data (e.g. numbers of specialists), please do not hesitate to state an estimated number or range. This can be detailed later, if necessary.

It will not be an exception that the situation in your country is in the process of change (e.g. merging of societies, laws being changed). Please state so when the present situation is bound to change.

COUNTRY :

CONTACT: name and e-mail address:

NAME OF YOUR SPECIALTY in your own language:

1. General information, number of laboratory specialists.

Please describe the present situation in your country of the field of clinical chemistry/laboratory medicine. As described above, central to the questionnaire is clinical chemistry. This field might be difficult to define precisely, as (sub)specialties are grouped quite differently across European countries. Please describe:-

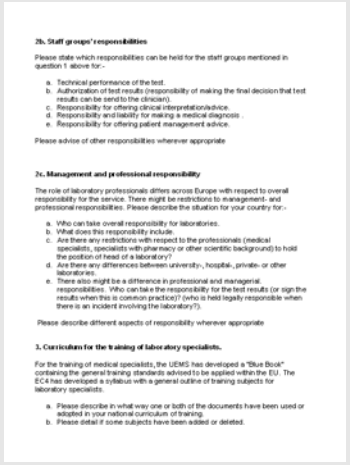
a. The names of staff groups able to practice in clinical chemistry (medical, pharmaceutical, scientific background).
b. The (estimated) numbers in each group.
c. The grades of staff within each group.
d. Qualifications, include grade of qualification, required to practice, including the need for scientific and/or pharmacy-related qualifications.
e. In some countries, people with academic training, please state level of qualification, without additional specialization work in the clinical laboratory (sometimes referred to as "technologists"). Please state if these do exist in your country and how many.

Questions relating to scope of practice are addressed in question 2b)

2a. responsibilities and fields of interest within laboratory specialties

As specialties are defined differently across Europe, we ask you to define your specialty in more detail. Please make the description taking account of the following items: what are the fields of interest that in your country commonly are under responsibility of clinical chemistry laboratory professionals (respectively specialists (medical, scientific, pharmacist), technologists).
Please state if specialists trained in pharmacy or other scientific background can or do have different interests or responsibilities. There might be a difference between fields of interest that are part of the specialist training (please state if fields are part of the training or not), and if these fields of interest are generally part of day-to-day responsibility.
Most commonly, what is trained will be practiced. However, some fields could be trained, but not practiced, or could be practiced without training.
Please take into account the following fields of interest. These fields are defined in more detail (as an example), because a single word might not give enough information. Certain fields might however be defined quite differently in your country. If this is the case, please describe this situation.

Routine haematology:	Hb, blood smears,
Special haematology:	haemoglobinopathies
Bone marrow:	evaluating bone marrow smears
Cellular immunology:	flow cytometry
Coagulation:	(INR, APTT)
Transfusion: (excluding collection of blood)	transfusion serology, supply of donor blood
Blood banking:	collecting blood from donors, preparing donor blood
Biochemistry:	routine tests Na, K, BNP, cardiac markers, proteins,
M-proteins, tumour markers	
Endocrinology:	thyroid, cortisol, PTH, FH, LH
Toxicology:	ethanol, barbiturates, opiates, paracetamole
Therapeutic drug monitoring:	digoxin, gentamicin
Immunology:	IgG/A/M, allergy tests, autoimmune testing, anti-
nuclear antibodies, cytokines, complement	
Cellular immunology:	flow cytometry
Microbiology:	bacteriology, virology, mycology, parasitology.
Serology:	hepatitis ABC, Epstein Barr etc.
Genetics: DNA-testing	haemochromatosis, thalassemia
IVF, semen	semen analysis, preparation semen, IVF



2b. Staff groups' responsibilities

Please state which responsibilities can be held for the staff groups mentioned in question 1 above for:-

a. Technical performance of the test.
b. Authorization of test results (responsibility of making the final decision that test results can be send to the clinician).
c. Responsibility for offering clinical interpretation/advice.
d. Responsibility and liability for making a medical diagnosis .
e. Responsibility for offering patient management advice.

Please advise of other responsibilities wherever appropriate

2c. Management and professional responsibility

The role of laboratory professionals differs across Europe with respect to overall responsibility for the service. There might be restrictions to management- and professional responsibilities. Please describe the situation for your country for:-

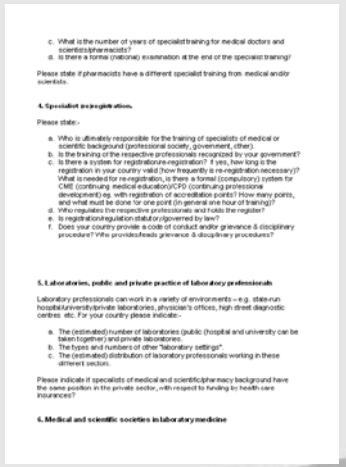
a. Who can take overall responsibility for laboratories.
b. What does this responsibility include.
c. Are there any restrictions with respect to the professionals (medical specialists, specialists with pharmacy or other scientific background) to hold the position of head of a laboratory?
d. Are there any differences between university-, hospital-, private- or other laboratories.
e. There also might be a difference in professional and managerial responsibilities. Who can take the responsibility for the test results (or sign the results when this is common practice)? (who is held legally responsible when there is an incident involving the laboratory?).

Please describe different aspects of responsibility wherever appropriate

3. Curriculum for the training of laboratory specialists.

For the training of medical specialists, the UEMS has developed a "Blue Book" containing the general training standards advised to be applied within the EU. The EC4 has developed a syllabus with a general outline of training subjects for laboratory specialists.

a. Please describe in what way one or both of the documents have been used or adopted in your national curriculum of training.
b. Please detail if some subjects have been added or deleted.



c. What is the number of years of specialist training for medical doctors and scientists/pharmacists?
d. Is there a formal (national) examination at the end of the specialist training?

Please state if pharmacists have a different specialist training from medical and/or scientists.

4. Specialist re-registration.

Please state:-

a. Who is ultimately responsible for the training of specialists of medical or scientific background (professional society, government, other).
b. Is the training of the respective professionals recognized by your government?
c. Is there a system for registration/re-registration? If yes, how long is the registration in your country valid (how frequently is re-registration necessary)? What is needed for re-registration, is there a formal (compulsory) system for CME (continuing medical education)/CPD (continuing professional development) eg. with registration of accreditation points? How many points, and what must be done for one point (in general one hour of training)?
d. Who regulates the respective professionals and holds the register?
e. Is registration/regulation statutory/governed by law?
f. Does your country provide a code of conduct and/or grievance & disciplinary procedure? Who provides/leads grievance & disciplinary procedures?

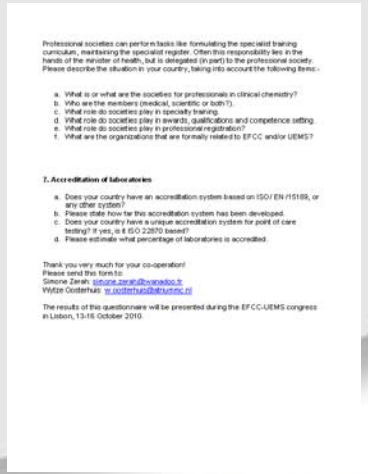
5. Laboratories, public and private practice of laboratory professionals

Laboratory professionals can work in a variety of environments – e.g. state-run hospital/university/private laboratories, physician's offices, high street diagnostic centres etc. For your country please indicate:-

a. The (estimated) number of laboratories (public (hospital and university can be taken together) and private laboratories.
b. The types and numbers of other "laboratory settings".
c. The (estimated) distribution of laboratory professionals working in these different sectors.

Please indicate if specialists of medical and scientific/pharmacy background have the same position in the private sector, with respect to funding by health care insurances?

6. Medical and scientific societies in laboratory medicine



Professional societies can perform tasks like formulating the specialist training curriculum, maintaining the specialist register. Often this responsibility lies in the hands of the minister of health, but is delegated (in part) to the professional society. Please describe the situation in your country, taking into account the following items:-

a. What is or what are the societies for professionals in clinical chemistry?
b. Who are the members (medical, scientific or both?).
c. What role do societies play in specialty training.
d. What role do societies play in awards, qualifications and competence setting.
e. What role do societies play in professional registration?
f. What are the organizations that are formally related to EFCC and/or UEMS?

7. Accreditation of laboratories

a. Does your country have an accreditation system based on ISO / EN /15189, or any other system?
b. Please state how far this accreditation system has been developed.
c. Does your country have a unique accreditation system for point of care testing? If yes, is it ISO 22870 based?
d. Please estimate what percentage of laboratories is accredited.

Thank you very much for your co-operation!
Please send this form to:
Simone Zerah: simone.zerah@wanadoo.fr
Wytze Oosterhuis: w.oosterhuis@atriumnc.nl

The results of this questionnaire will be presented during the EFCC-UEMS congress in Lisbon, 13-16 October 2010.

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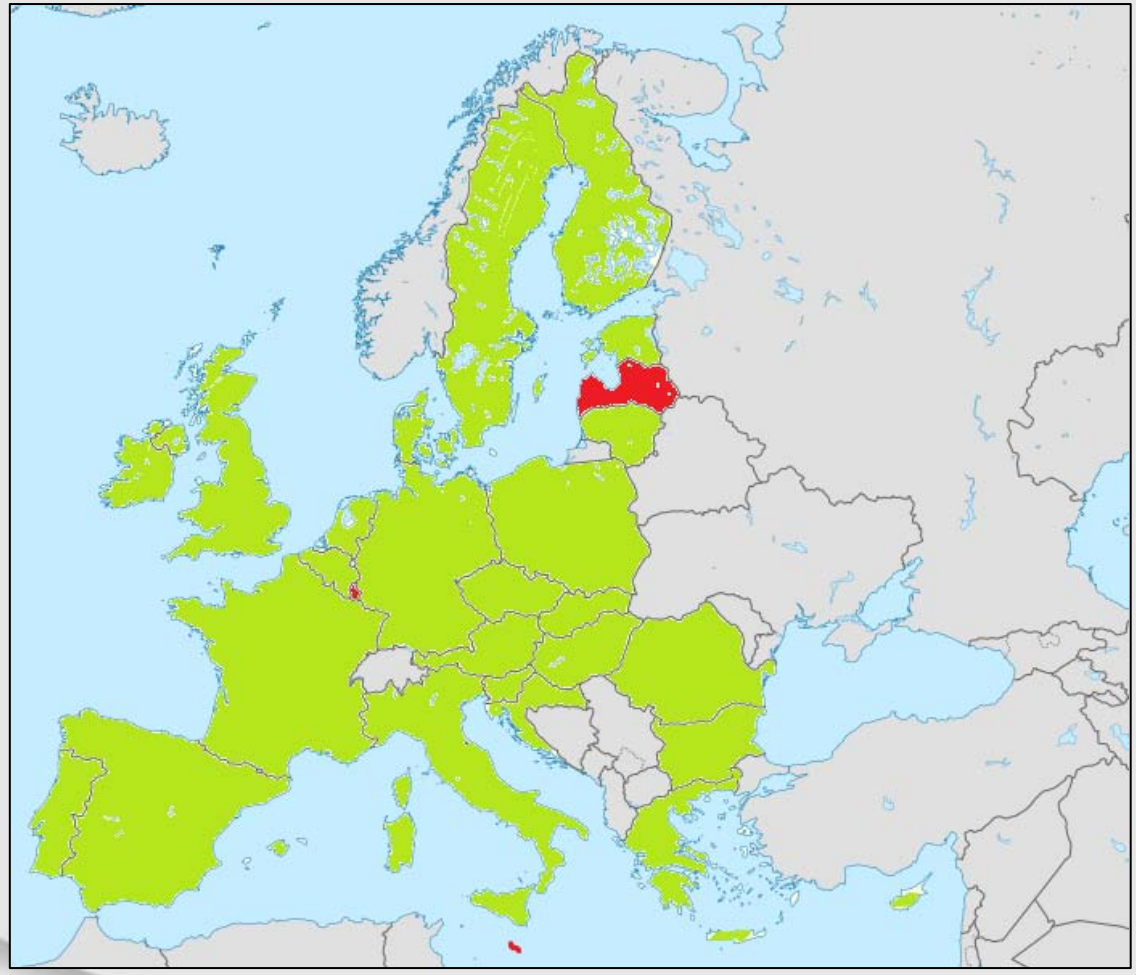
Response EU countries



Response:
25/28 countries = 89%
494/501 mil. = 98,6%

Red = no response

Names: Clinical, (bio)chemistry, diagnostic, medical, laboratory EFLM (2010): Specialist in Laboratory Medicine

Table 1 Names of specialties and EFLM/IFCC member societies in the European Union countries.

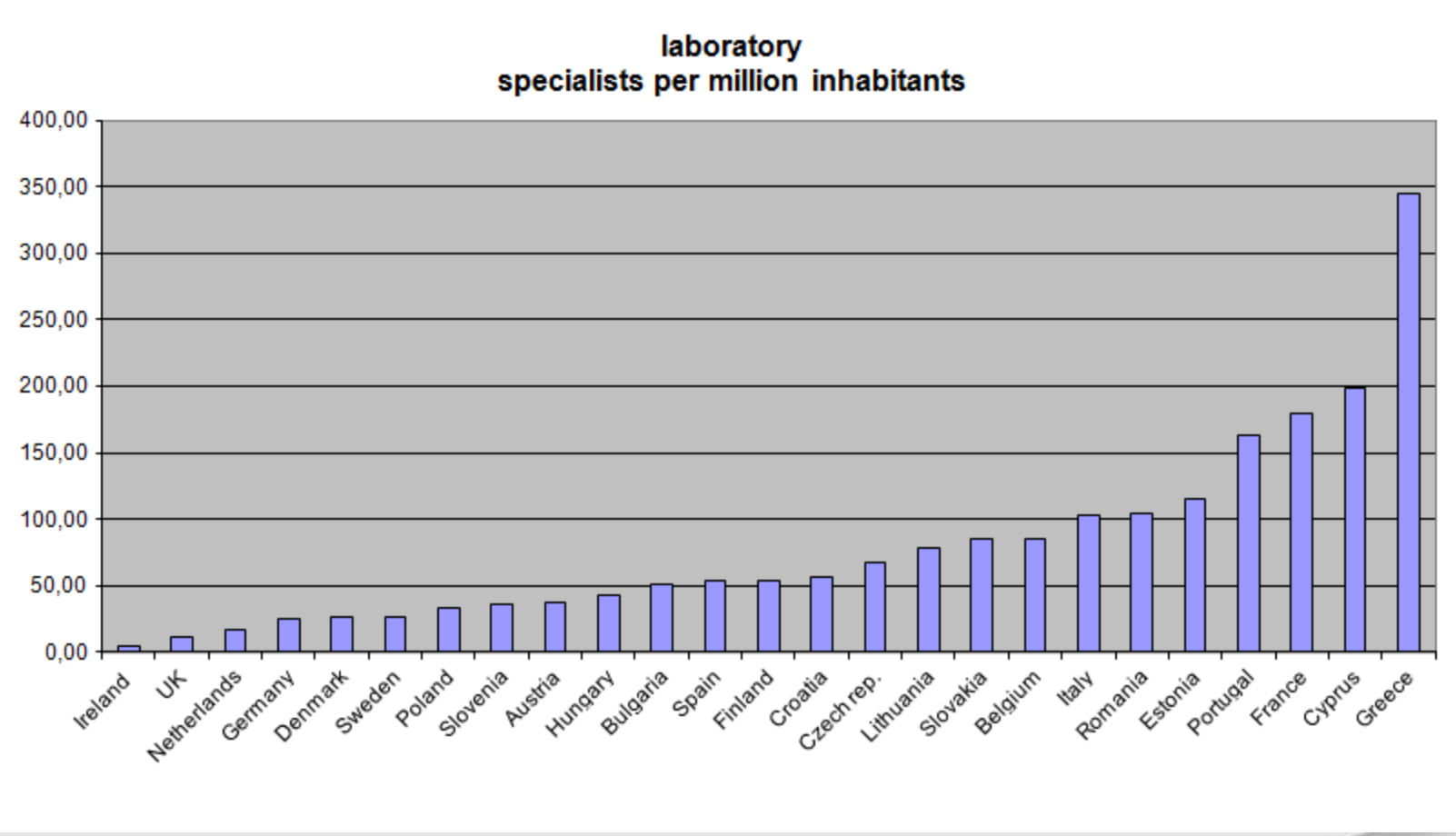
EU countries	Name specialty	Name professional society (member EFLM) (4,5)
1. Austria	Medizinische und Chemische Labordiagnostik	Österreichische Gesellschaft für Laboratoriumsmedizin und Klinische Chemie (ÖGLKMC)
2. Belgium	Biologie Clinique; Klinische Biologie	Société Royale Belge de Chimie Clinique, Belgische Vereniging voor Klinische Chemie (KBVKC, SRBCC)
3. Bulgaria	клинична лаборатория (Clinical Laboratory)	Bulgarian Society of Clinical Laboratory
4. Croatia	Specijalist Medicinske Biokemije i Laboratorijske Medicine	Hrvatsko društvo za medicinsku biokemiju i laboratorijsku medicinu (HDMBLM)
5. Cyprus	ΚΛΙΝΙΚΟΣ ΧΗΜΙΚΟΣ (Clinical Chemistry)	Association of Clinical Laboratory Directors, Biomedical and Clinical Laboratory Scientists (ACLDBCLS)
6. Czech Republic	Klinická Biochemie	Česká společnost klinické biochemie (ČSKB)
7. Denmark	Klinisk Biokemi	Dansk Selskap for Klinisk Biokemi (DSKB)
8. Estonia	Laborimeditsiin	Eesti Laborimeditsiini Ühing (ESLM)
9. Finland	Kliininen Kemia Sairaalakemisti	Suomen Kliinisen Kemian Yhdistys (SKKY)
10. France	Biologie Médicale	Societé Francaise de Biologie Clinique (SFBC)
11. Germany	Laboratoriumsmedizin	Deutsche Vereinte Gesellschaft für Klinische Chemie und Laboratoriumsmedizin e.V. (DGKL)
12. Greece	Κλινική Χημεία-Κλινική Βιοχημεία	Greek Soc.Clin. Chem.Clin. Biochem. (EEKX-KB)
13. Hungary	Orvosi Laboratóriumi Diagnosztika	Magyar Laboratóriumi Diagnosztikai Társasag (MLDT)
14. Ireland	Clinical Biochemistry, Clinical Chemistry	Association of Clinical Biochemists in Ireland (ACBI)
15. Italy	Biochimica Clinica	Società Italiana di Biochimica Clinica e Biologia Molecolare Clinica (SIBIOC)
16. Latvia	Laboratora Medicına	Latvijas Laboratorijas Specialistu biedriba (LSB)
17. Lithuania	Laboratorine Medicine	Lithuanian Society Laboratory Medicine
18. Luxembourg	Biologie Clinique/Biochemie	Societé Luxembourgeoise de Biologie Clinique (SLBC)

Types of laboratory specialists in EU

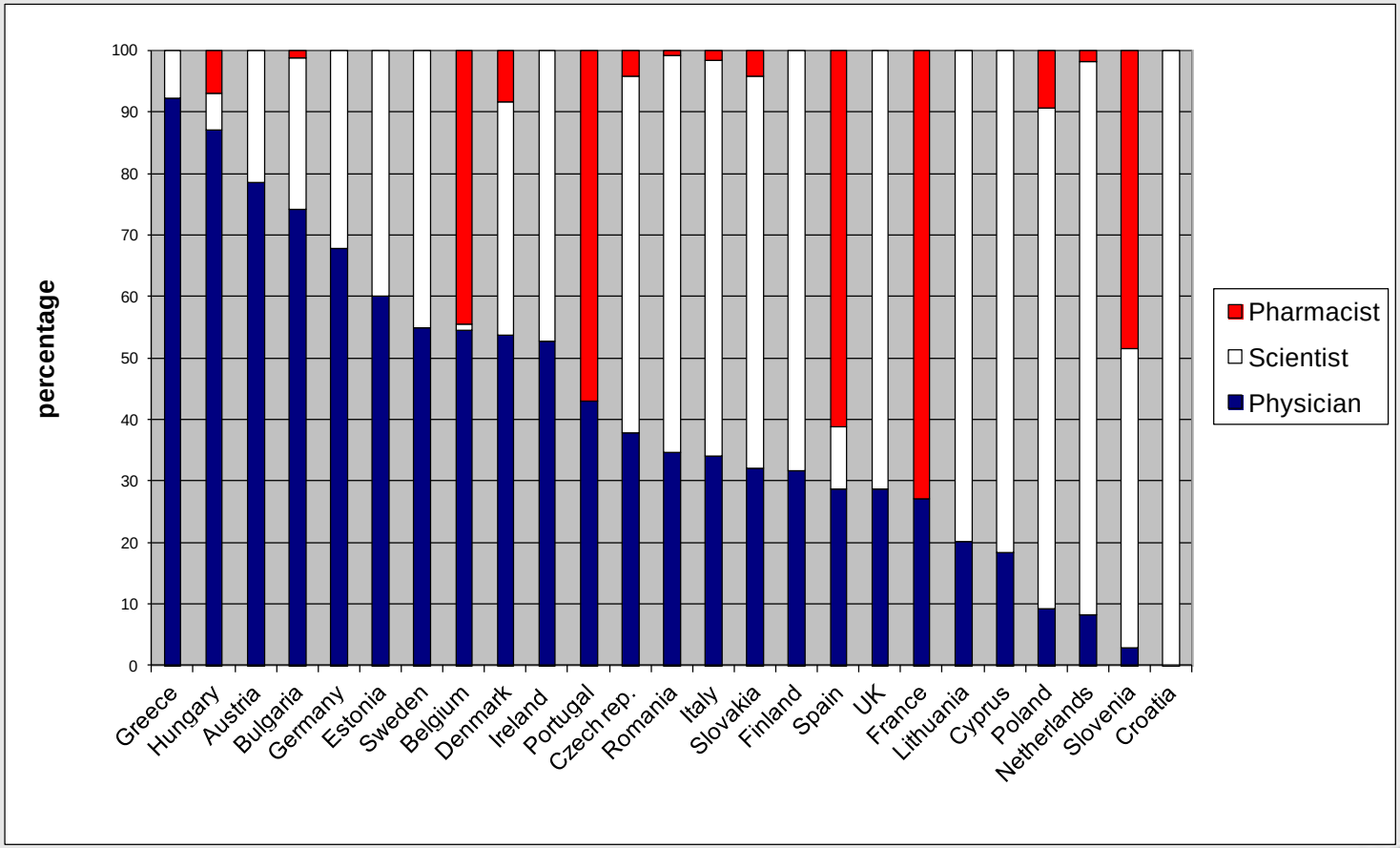
Totals EU:		
Physicians:	**14.800**	**(41%)**
Pharmacists:	**11.300**	**(31%)**
Scientists:	**10.200**	**(28%)**
Total:	**36.300**	**(100%)**

+

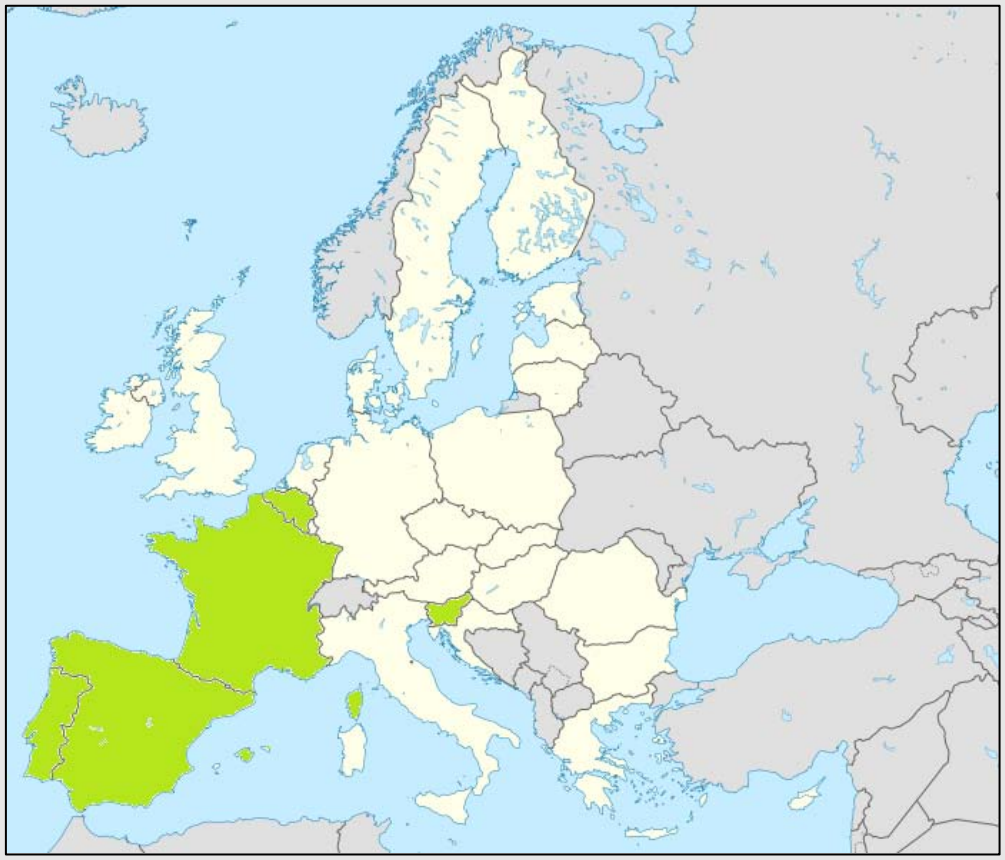
Number of laboratory specialists



Types of laboratory specialists



Countries with high number of pharmacists



France:	73%
Spain:	61%
Portugal:	57%
Slovenia:	49%
Belgium:	45%

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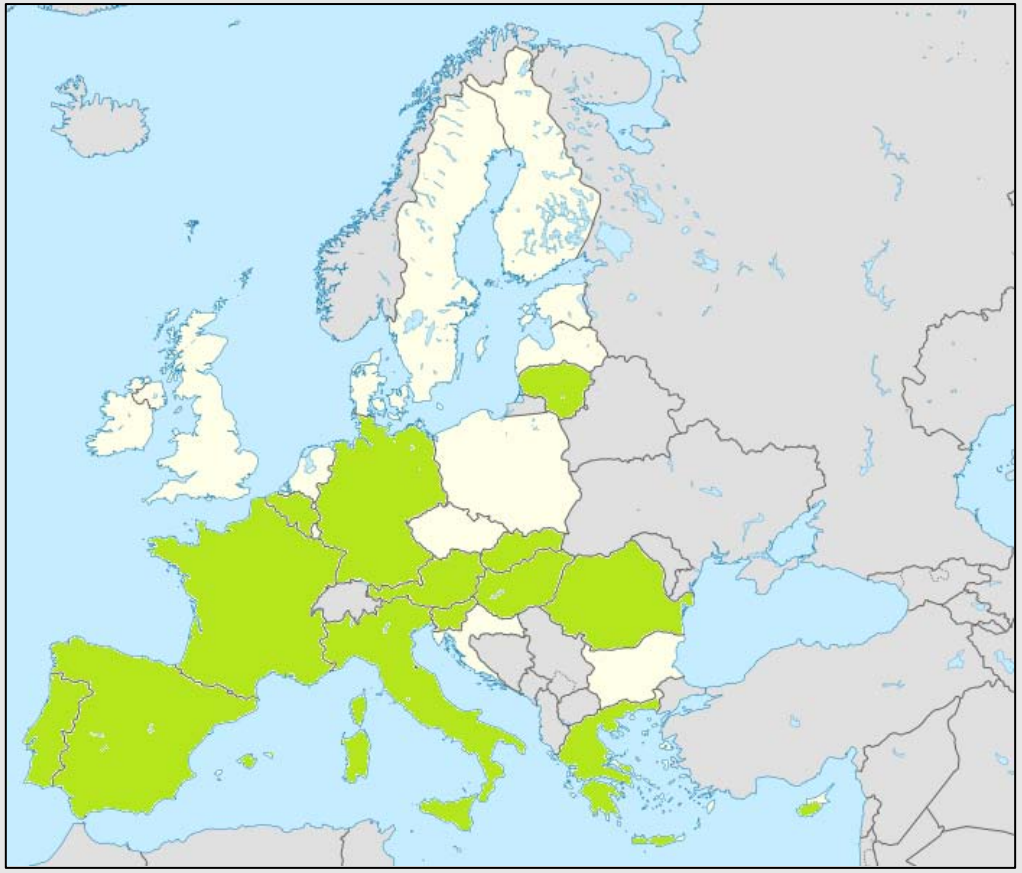
Fields covered by clinical chemistry/laboratory medicine

	% of countries	
Biochemistry:	100%	(25/25)
Endocrienology:	96%	(24/25)
Haematology:	92%	(23/25)
Microbiology:	52%	(13/25)
Transfusion:	42%	(10/25)

Not always the same responsibility for MDs, scientists, pharmacists

Countries with general laboratory medicine



General/polyvalent = biochemistry + hematology + microbiology

60% countries (15/25)

83% of EU laboratory specialists in “polyvalent” countries

Restrictions for laboratory professionals

Table 4 Position of scientists and pharmacists compared to physicians.

	Scientist	Pharmacist
1. Austria	Limited	NA[a]
2. Belgium	NA[a]	Not limited
3. Bulgaria	Limited	limited
4. Croatia	Not limited	NA[a]
5. Cyprus[a]	Not limited	NA[a]
6. Czech Republic	Not limited	Not limited
7. Denmark	Limited	Limited
8. Estonia	Limited	Limited
9. Finland	Limited	NA[a]
10. France	NA[a]	Not limited
11. Germany	Limited	NA[a]
12. Greece	Limited[b]	NA[a]
13. Hungary	Limited	Limited
14. Ireland	Not limited	NA[a]
15. Italy	Not limited	Not limited
16. Latvia	–	–
17. Lithuania	Not limited	NA[a]
18. Luxembourg	–	–
19. Malta	–	–
20. Netherlands	Not limited	Not limited
21. Poland	Not limited	Not limited
22. Portugal	Limited[c]	Not limited
23. Romania	Not limited	Not limited
24. Slovak Republic	Not limited	Not limited
25. Slovenia	Not limited	Not limited
26. Spain	Not limited	Not limited
27. Sweden	Limited	NA[a]
28. UK	Not limited	NA[a]

NA, not applicable; [a]No specialists, or very limited number; [b]only MD can be end responsible in private laboratory; [c]Not allowed to assume the position of technical director of a laboratory.

Countries with restrictions for specialists other than MD:
Scientists: not limited 14/25, limited 9/25, NA 2
Pharmacists: not limited 11/25, limited 4/25, NA 10

- Only MD head of laboratory (e.g. Bulgaria, Portugal)
- Only under responsibility of MD (e.g. Germany, Sweden)
- Larger laboratories only MD (e.g. Hungary)
- Scientists cannot own private laboratory (e.g. Greece)

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Special cases:

France, Belgium:
Pharmacists and Physicians have the same position by law.

Spain:
A new law in 2014:

- The monovalent specialties *bioquímica clínica* and *the polyvalent* specialty *análisis clínicos* vanish.
- One new polyvalent specialty in laboratory medicine.
- This specialty training will accept students with training in medicine, pharmacy, biology and (bio)chemistry.

Clin Chem Lab Med 2012;50(8):1317–1328 © 2012 by Walter de Gruyter • Berlin • Boston. DOI 10.1515/cclm-2012-0019

The EC4 European Syllabus for Post-Graduate Training in Clinical Chemistry and Laboratory Medicine: version 4 – 2012

U.E.M.S.

Recommended Standards for Training Specialists in Laboratory Medicine - Medical Biopathology

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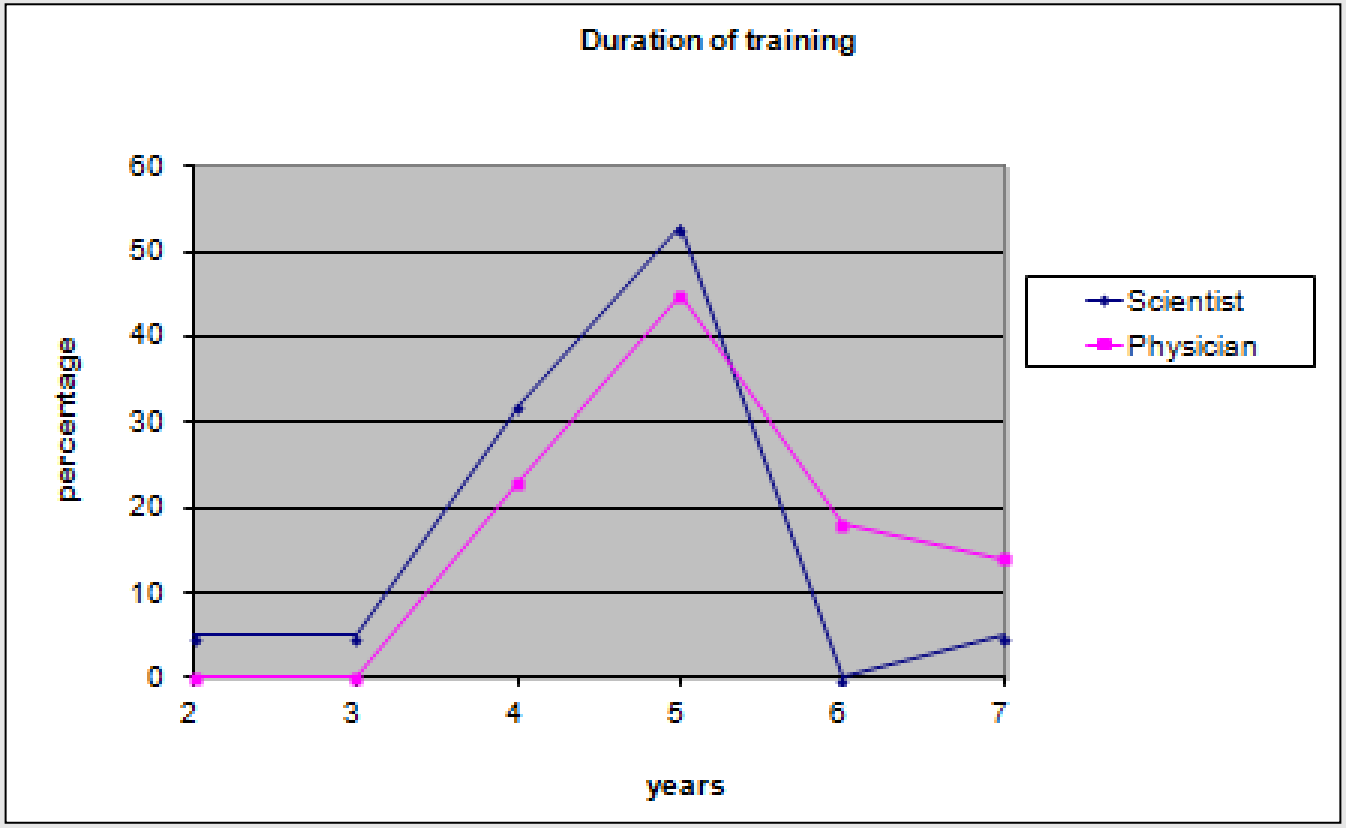
EC4/UEMS curriculum used?

EC4: 64% (16/25) of countries

- sometimes only for scientists/pharmacists
- curriculum predates EC4 (UK, Ireland)

UEMS “Blue Book” used in 5 countries.
- Hungary, Finland, Portugal and Slovakia
- curriculum adapted according to Swedish situation.

Duration specialist training



Median Scientists=Physicians

Formal examination in training

Physicians:	yes:	77% (16/22)
	no:	23% (5/22)

Other: 2 (Cyprus, Netherlands: no medical specialist training of physicians)

Scientists:	yes:	65% (13/21)
	no:	35% (8/21)

Greece: voluntary examination;
other: 3 (Cyprus: no training; France, Belgium: no specialists, or very limited number)

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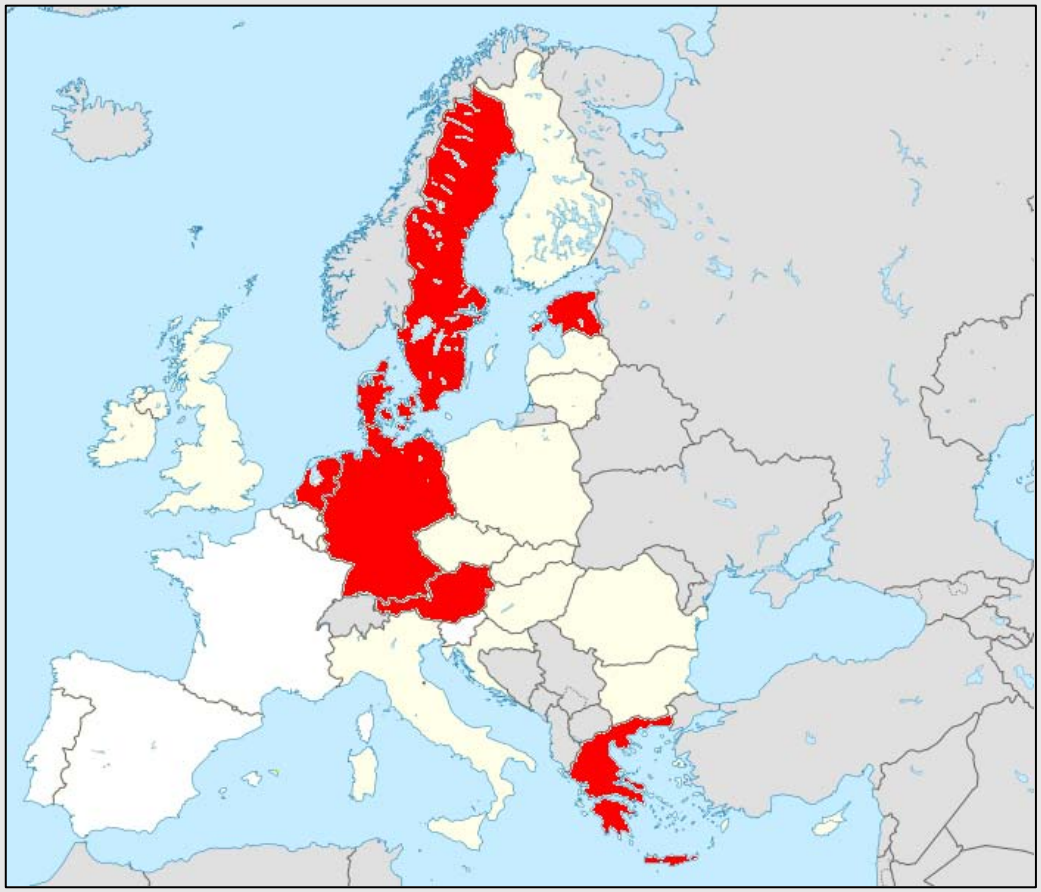
Formal recognition of laboratory specialists-scientists

Scientists:	yes:	70% (16/23)
	no:	30% (7/23)

France, Belgium: no specialists, or very limited number

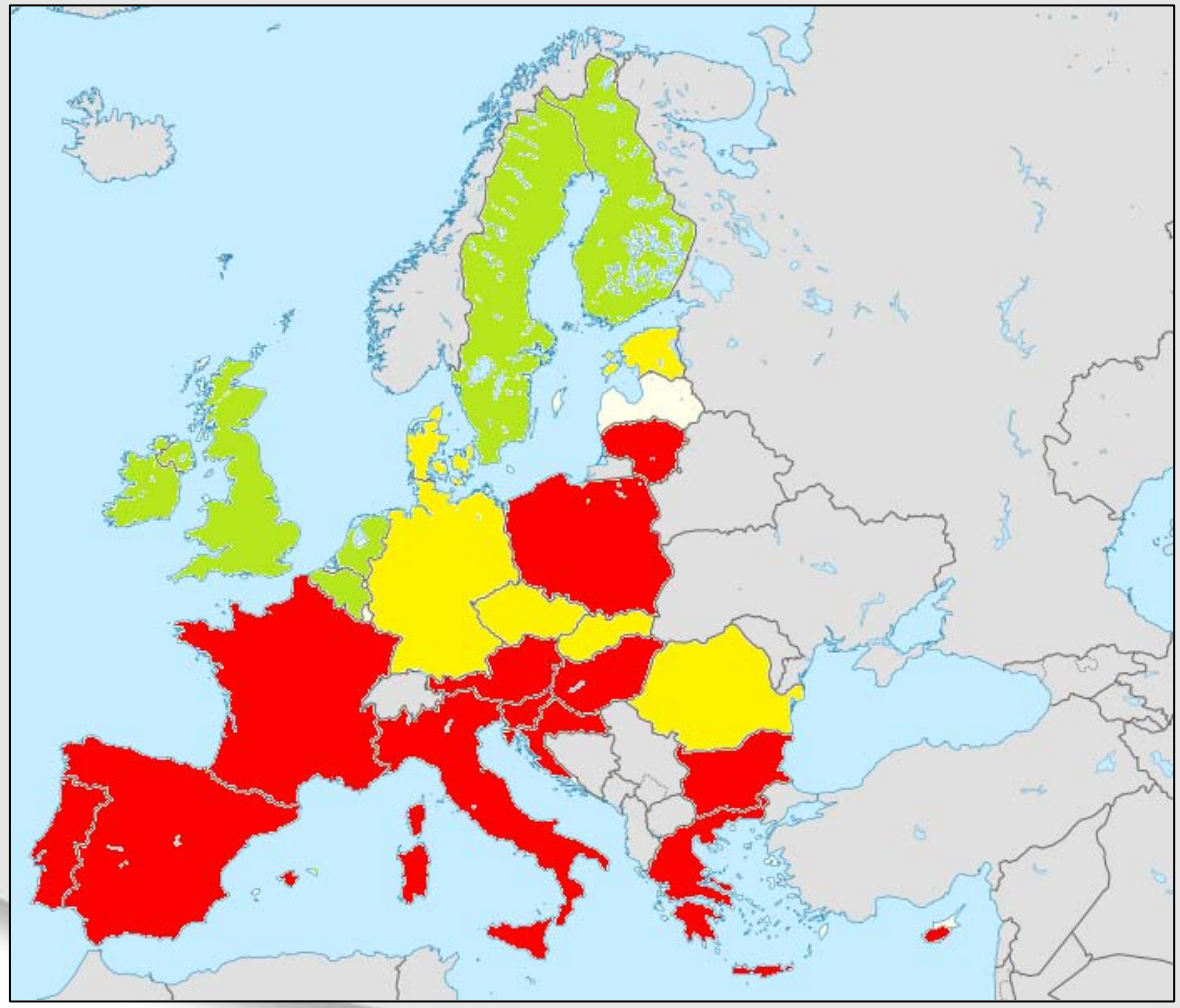
Pharmacists: recognized in Belgium, France, Portugal, Slovenia and Spain.

Recognition of laboratory specialists (scientists)



No formal recognition

Accreditation according to ISO 15189



<10%

10-75%

>75%

“Blue Book”


U.E.M.S.
Section of Laboratory Medicine/Medical Biopathology
Recommended Standards for Training Specialists in Laboratory Medicine/Medical Biopathology
May 2012

Content Blue Book

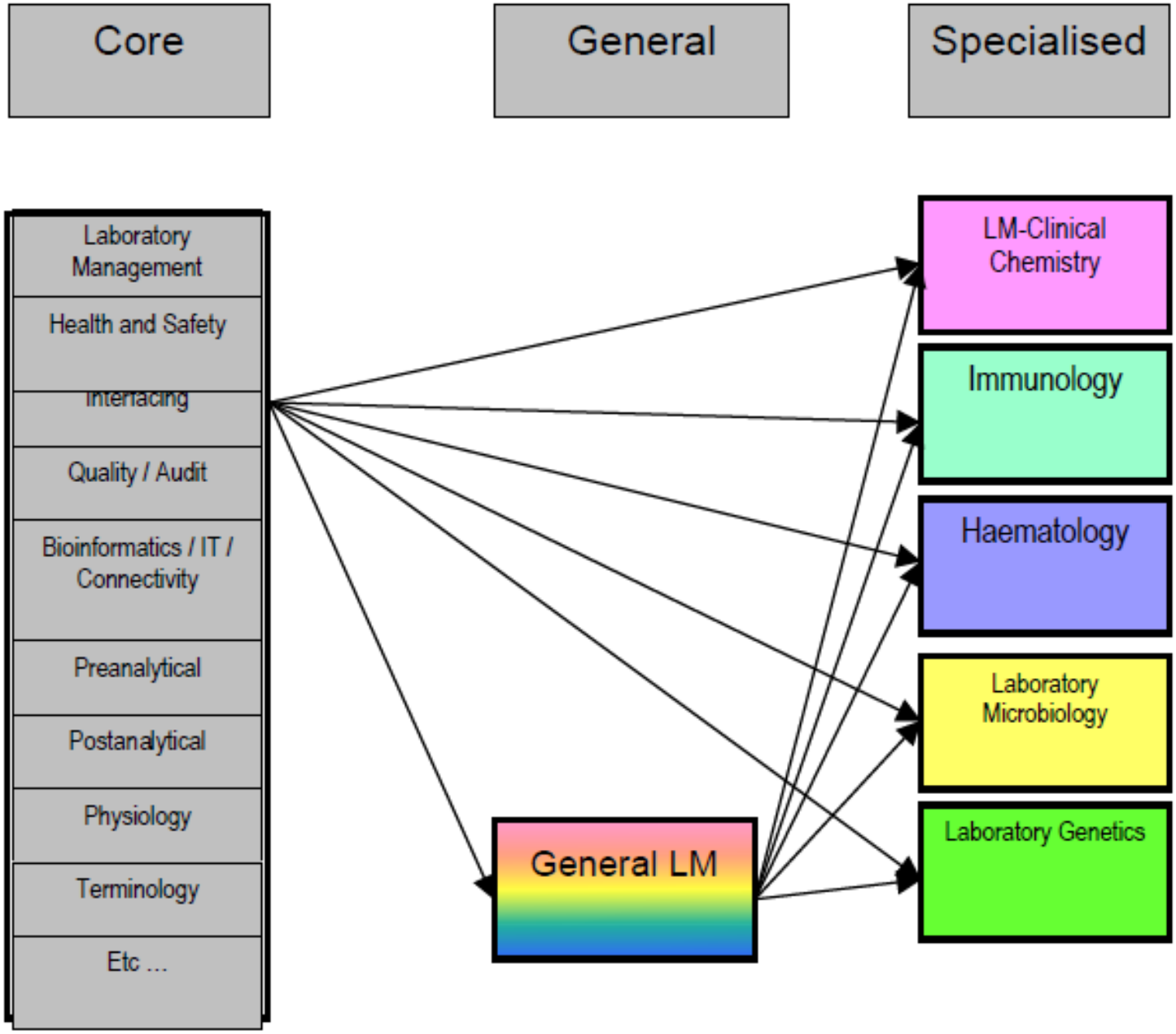
“Blue Book”

Overlap between specialties

- specialties are defined differently from country to country within the EU.

- The clinical component of practice varies among different specialties.

These differences between EU countries make it a particularly challenging task to harmonize specialist training within the EU.


Core
General
Specialised
Laboratory Management
Health and Safety
Interfacing
Quality / Audit
Bioinformatics / IT / Connectivity
Preanalytical
Postanalytical
Physiology
Terminology
Etc ...
General LM
LM-Clinical Chemistry
Immunology
Haematology
Laboratory Microbiology
Laboratory Genetics

May 8 2012 Lena Norlund, Rob Jansen

Declaration for a Vision for Specialization in Laboratory Medicine in Europe

Formulated in Prague 120318 by UEMS and EFLM

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Vision and Declaration

- highly competitive markets..
- we need to develop teams...
- based on a collaborative approach...
- understanding both the shared need for education, for the core competences of scientists and physicians...
- understanding the present status and starting point in each participating country.

- laboratories require both general and super specialized specialists in laboratory medicine...
- a vision of a polyvalent knowledge base (a common trunk of education and training) is...
- a combined education for people with different backgrounds also leads to increase cross-fertilisation and with that the symbiotic production of new knowledge.

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Statement

With this common vision, our two associations UEMS and EFLM agree upon working together towards a more efficient and competent medical laboratory.

Challenges

1. Agree on the name of our profession.
2. Write the Blue Syllabus.
3. Define a common strategy towards the European Commission on the harmonization of our profession.

Conclusion and discussion

- Large differences between countries
- Task for both EFLM and UEMS in harmonization of specialties within EU
- Periodic update of data?

Representation of specialists by EFCC and UEMS

Member societies EFCC are mixed (MD+PhD)
yes: 100% of countries
no: 0%
(missing: 2)

Member societies EFCC = UEMS
yes: 33% of countries
no: 67%
(missing: 5)

The role of the physician in laboratory medicine: a European perspective

Siraj A Misbah,[1] Vana Kokkinou,[2] Katie Jeffery,[3] Wytze Oosterhuis,[4] Brian Shine,[5] Anna Schuh,[6] Theodore Theodoridis[2]

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UEMS: EU free movement of persons

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Table 3. Fields of interest

	Biochem.	Endocrien.		Immunol.	Hematol.		Transfusion Microbiol.
1. Austria	**yes**	**yes**	**yes**	**yes**	**yes**	**yes**	
2. Belgium	**yes**	**yes**	**yes**	**yes**	**yes**	**yes**	
3. Bulgaria	yes	yes	yes	yes	no	no	
4. Cyprus	**yes**	**yes**	**yes**	**yes**	**part**	**yes**	
5. Czech Republic yes	yes	part	yes	no	no		
6. Denmark	yes	yes	yes	yes	no	no	
7. Estonia	yes	part	no	yes	yes	no	
8. Finland	**yes**	**yes**	**part**	**yes**	**yes**	**part**	
9. France	**yes**	**yes**	**yes**	**yes**	**yes**	**yes**	
10.Germany	yes	yes	yes	yes	no	yes	
11.Greece	**yes**	**yes**	**yes**	**yes**	**yes**	**yes**	
12.Hungary	yes	yes	yes	yes	no	yes	
13.Ireland	yes	yes	part	no	no	no	
14.Italy	yes	yes	yes	yes	no	yes	
15.Latvia	-	-	-	-	-	-	
16.Lithuania yes	**yes**	**yes**	**yes**	**part**	**yes**		
17.Luxembourg -	-	-	-	-	-		
18.Malta	-	-	-	-	-	-	
19.Netherlands yes	yes	yes	yes	yes	no		
20.Poland	yes	yes	yes	yes	part	no	
21.Portugal	yes	yes	yes	yes	no	yes	
22.Romania	**yes**	**yes**	**yes**	**yes**	**yes**	**yes**	
23.Slovak republic	**yes**	**yes**	**yes**	**yes**	**part**	**yes**	
24.Slovenia	yes	yes	yes	yes	no	yes	
25.Spain	yes	yes	no	yes	no	yes	
26.Sweden	yes	yes	part	yes	no	no	
27.UK	yes	yes	no	no	no	no	

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