Can we harmonize laboratory medicine in Europe?

EU Questionnaire
Clinical Chemistry

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Questionnaire UEMS-EFCC

- Sent to 27 EU countries (full members)
- UEMS and EFCC delegates
- March 2010

Differences EFCC - UEMS

Europe (EU)

- Full members: 27 countries
- Candidates: 4 (Croatia, Turkey, Iceland, Macedonia)
- Potential candidates: 5 (Albania, Bosnia-Herzegovina, Kosovo, Montenegro, Serbia)

Europe (UEMS)

- Full members: 30 (incl. Norway, Switzerland, Iceland)
- Associated members: 4 (Armeria, Croatia, Israel, Turkey)
- Observers: 2 (Azerbaijan, Georgia)

Europe (EFCC)

- Members: 39 countries

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Questionnaire

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 :

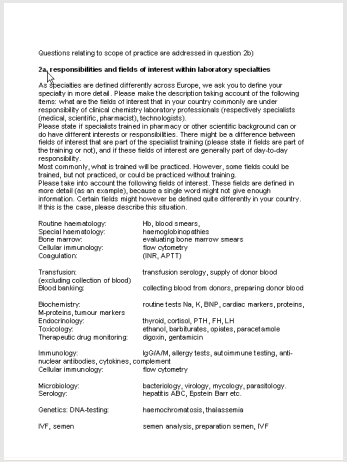
CONTACT: name and e-mail address:

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.

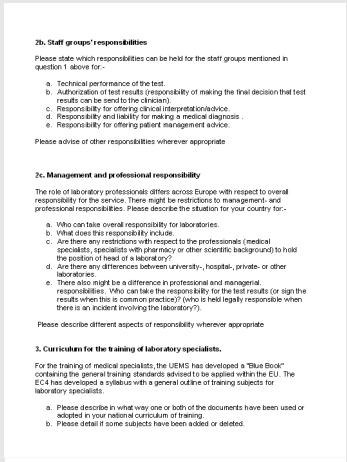


Questions relating to scope of practice are addressed in question 2b)

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:-

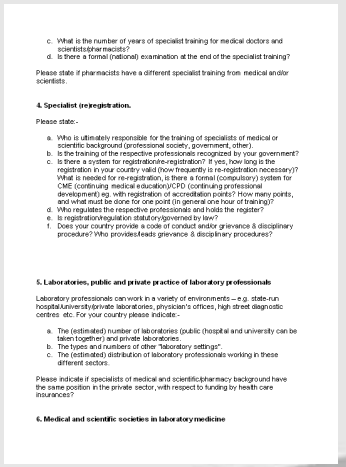
a. Who can take overal responsibility for laboratories.
b. What does this responsibility include.
c. Are there any restrictions with respect to the professionals (medical specialists, specialists with pharmacy or other scientific background) to hold the position of head of a laboratory?
d. Are there 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?

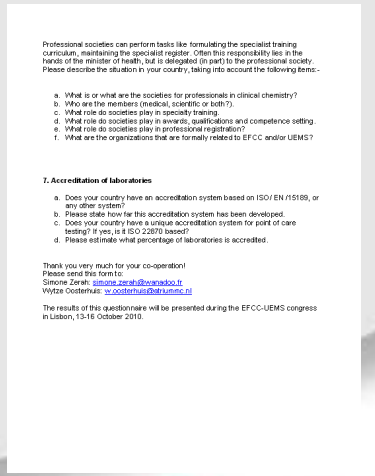
5. Laboratories, public and private practice of laboratory professionals

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@hrtumc.nl

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

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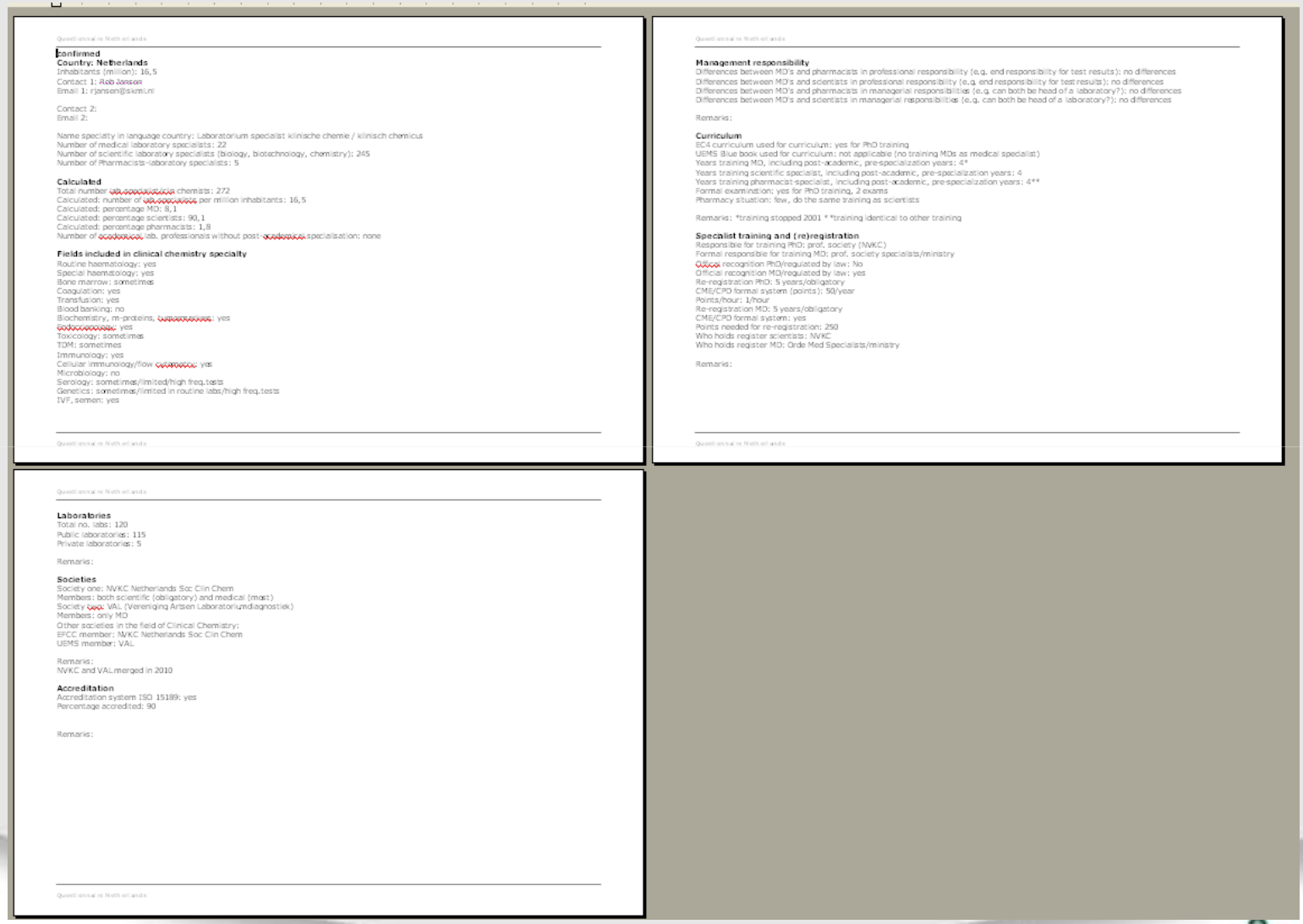
Questionnaire



confirmed
Country: Netherlands
Inhabitants (million): 16,5
Contact 1: Rob Jansen
Email 1: rjansen@skml.nl

Contact 2:
Email 2:

Name specialty in language country: Laboratorium specialist klinische chemie / klinisch chemicus
Number of medical laboratory specialists: 22
Number of scientific laboratory specialists (biology, biotechnology, chemistry): 245
Number of Pharmacists-laboratory specialists: 5

Calculated
Total number lab.specialists/clin chemists: 272
Calculated: number of lab.specialists per million inhabitants: 16,5
Calculated: percentage MD: 8,1
Calculated: percentage scientists: 90,1
Calculated: percentage pharmacists: 1,8
Number of academic lab. professionals without post-academic specialisation: none

Fields included in clinical chemistry specialty
Routine haematology: yes
Special haematology: yes
Bone marrow: sometimes
Coagulation: yes
Transfusion: yes
Blood banking: no
Biochemistry, rh-proteins, hormones: yes
Endocrinology: yes
Toxicology: sometimes
TDM: sometimes
Immunology: yes
Cellular immunology/flow cytometry: yes
Microbiology: no
Serology: sometimes/limited/high freq.tests
Genetics: sometimes/limited in routine labs/high freq.tests
IVF, semen: yes

Management responsibility
Differences between MD's and pharmacists in professional responsibility (e.g. end responsibility for test results): no differences
Differences between MD's and scientists in professional responsibility (e.g. end responsibility for test results): no differences
Differences between MD's and pharmacists in managerial responsibilities (e.g. can both be head of a laboratory?): no differences
Differences between MD's and scientists in managerial responsibilities (e.g. can both be head of a laboratory?): no differences

Remarks:

Curriculum
EC4 curriculum used for curriculum: yes for PhD training
UEMS Blue book used for curriculum: not applicable (no training MDs as medical specialist)
Years training MD, including post-academic, pre-specialization years: 4*
Years training scientific specialist, including post-academic, pre-specialization years: 4
Years training pharmacist-specialist, including post-academic, pre-specialization years: 4**
Formal examination: yes for PhD training, 2 exams
Pharmacy situation: few, do the same training as scientists

Remarks: *training stopped 2001 * *training identical to other training

Specialist training and (re)registration
Responsible for training PhD: prof. society (NVKC)
Formal responsible for training MD: prof. society specialists/ministry
Official recognition PhD/regulated by law: No
Official recognition MD/regulated by law: yes
Re-registration PhD: 5 years/obligatory
CME/CPD formal system (points): 50/year
Points/hour: 1/hour
Re-registration MD: 5 years/obligatory
CME/CPD formal system: yes
Points needed for re-registration: 250
Who holds register scientists: NVKC
Who holds register MD: Orde Med Specialists/ministry

Remarks:

Laboratories
Total no. labs: 120
Public laboratories: 115
Private laboratories: 5

Remarks:

Societies
Society one: NVKC Netherlands Soc Clin Chem
Members: both scientific (obligatory) and medical (most)
Society two: VAL (Vereniging Artsen Laboratoriumdiagnostiek)
Members: only MD
Other societies in the field of Clinical Chemistry:
EFCC member: NVKC Netherlands Soc Clin Chem
UEMS member: VAL

Remarks:
NVKC and VAL merged in 2010

Accreditation
Accreditation system ISO 15189: yes
Percentage accredited: 90

Remarks:

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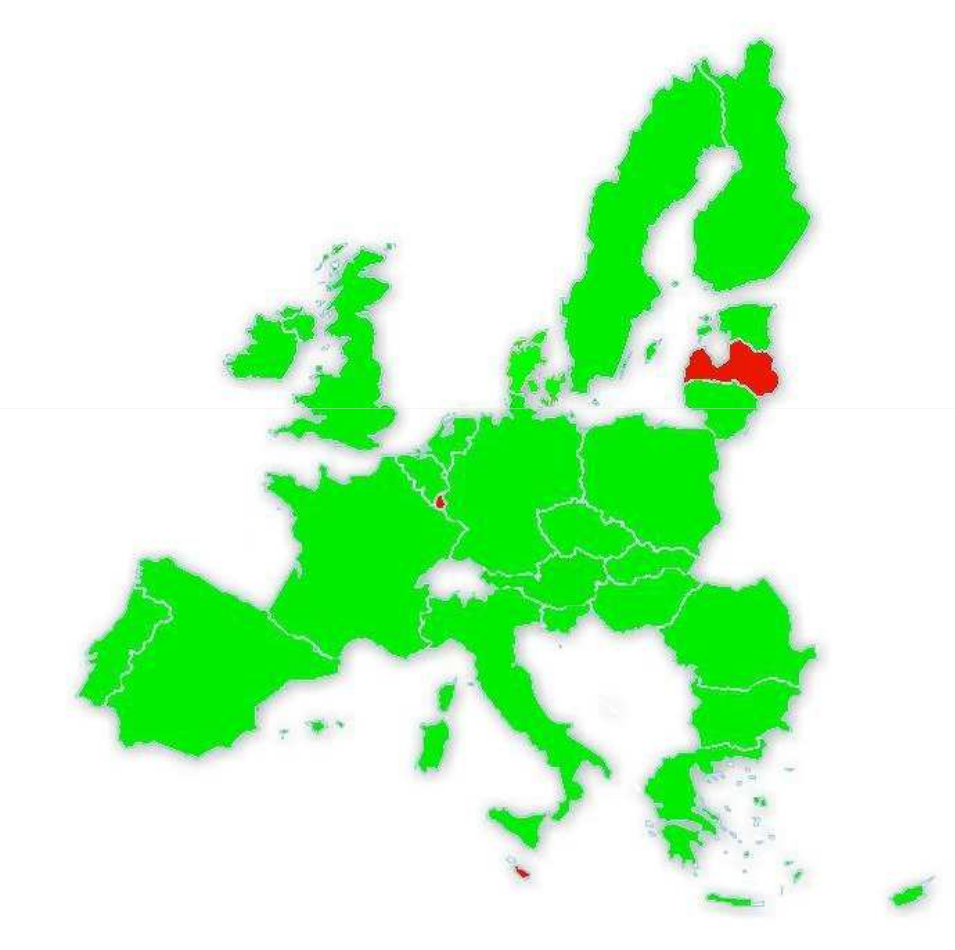
Response EU countries



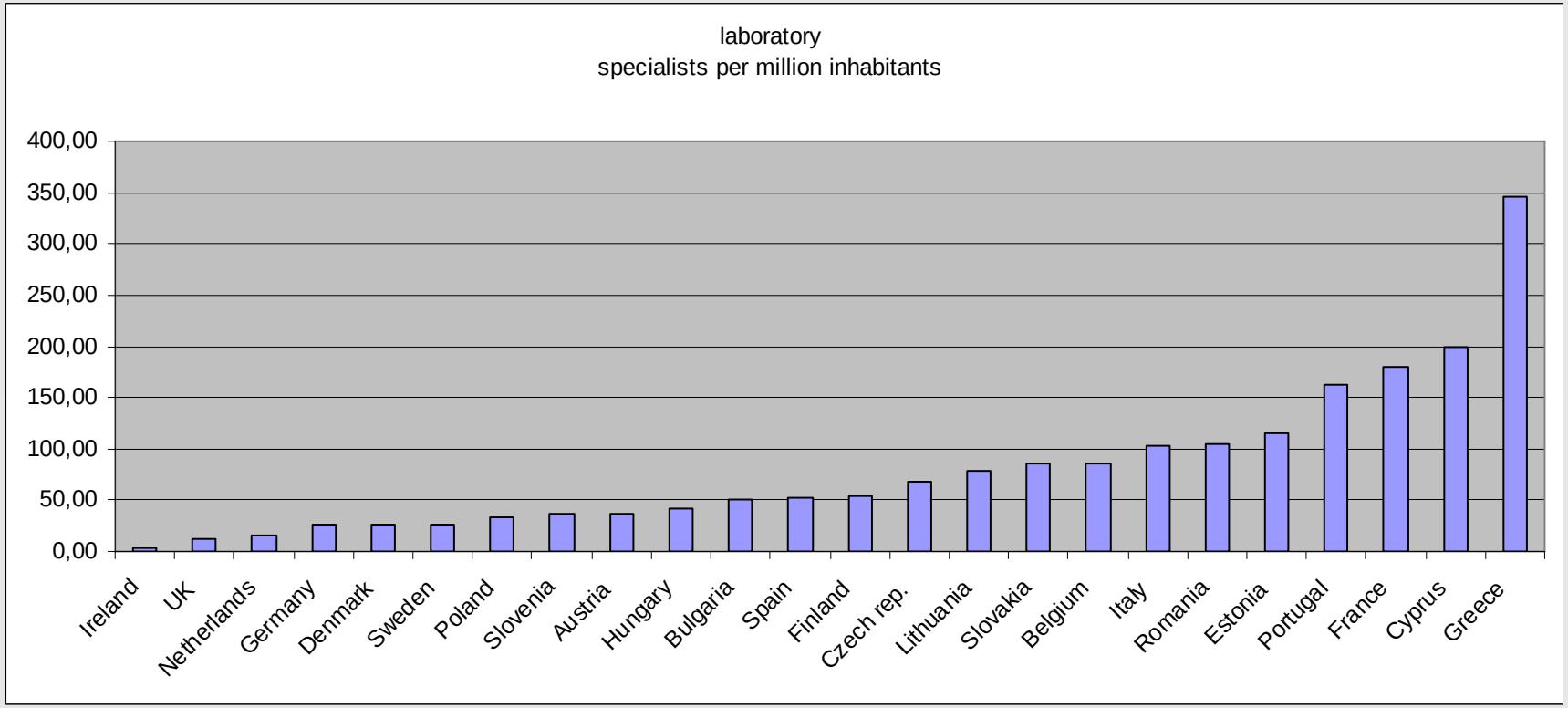
Response:
24/27 countries = 89%
490/497 mil. = 98,5%

Red = no response

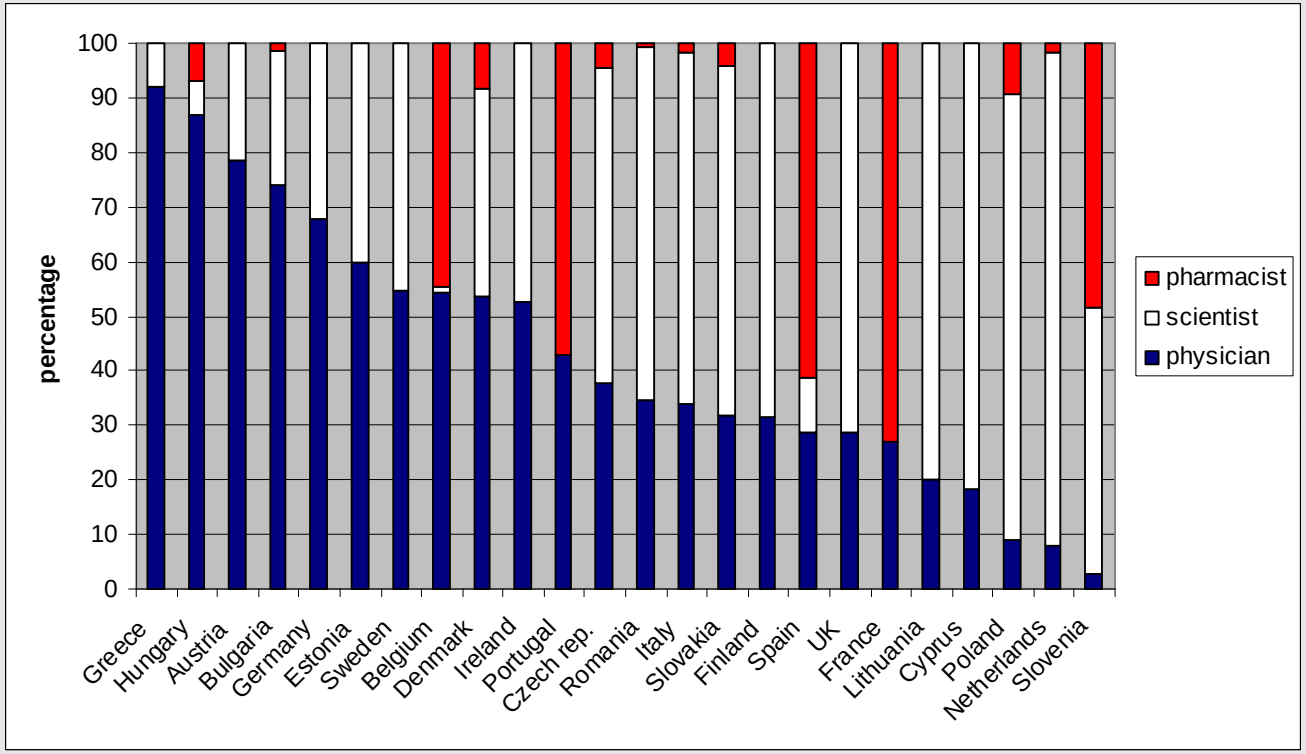
Types of laboratory specialists in EU

Totals EU:		
Physicians:	**14790**	**(41%)**
Pharmacists:	**11310**	**(31%)**
Scientists:	**10000**	**(28%)**
Total:	**36100**	**(100%)**

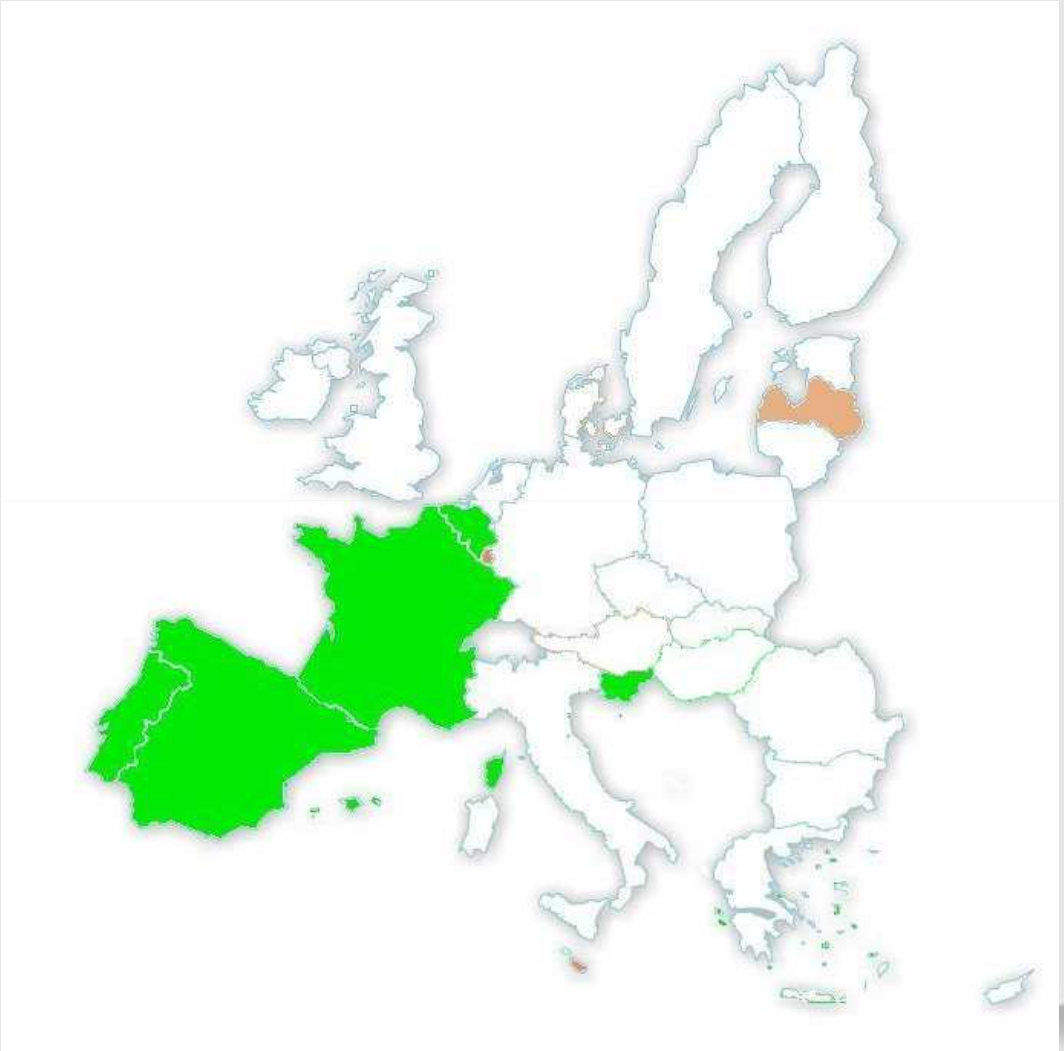
Number of laboratory specialists



Types of laboratory specialists



Countries with high number of pharmacists



Fields covered by clinical chemistry/laboratory medicine

	% of countries
Biochemistry:	100% (24/24)
Endocrienology:	96% (23/24)
Haematology:	92% (22/24)
Microbiology:	58% (14/24)
Transfusion:	42% (10/24)

Not always the same responsibility for MDs, scientists, pharmacists

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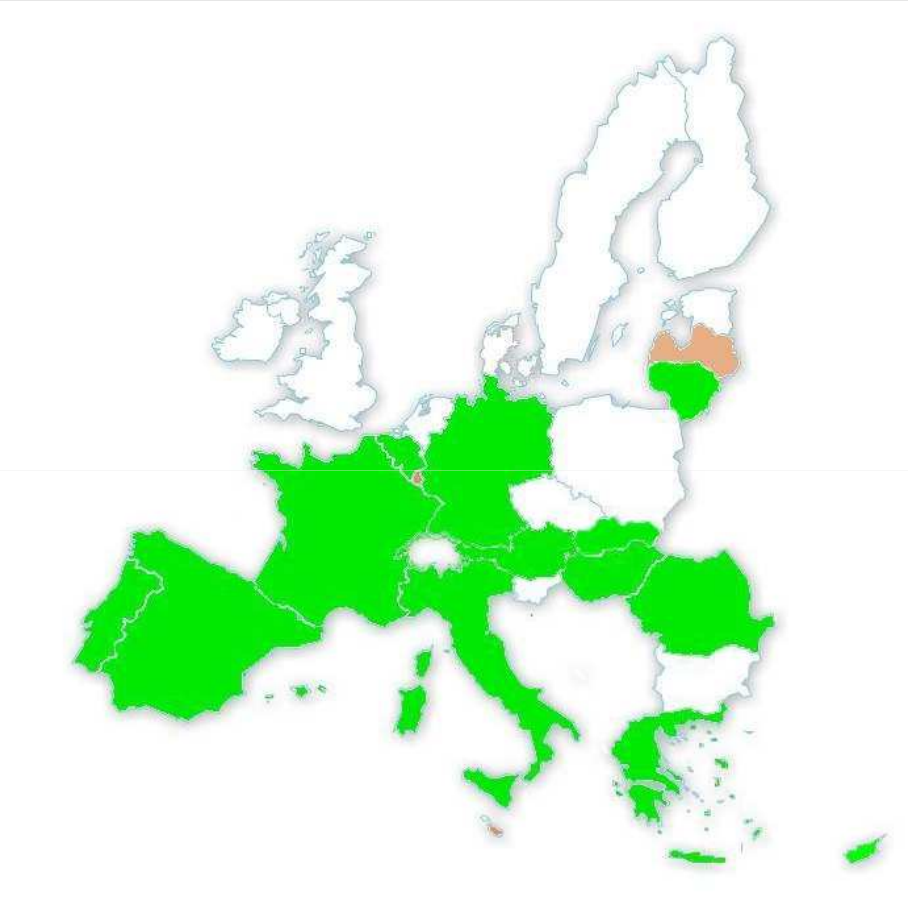
Countries with general laboratory medicine

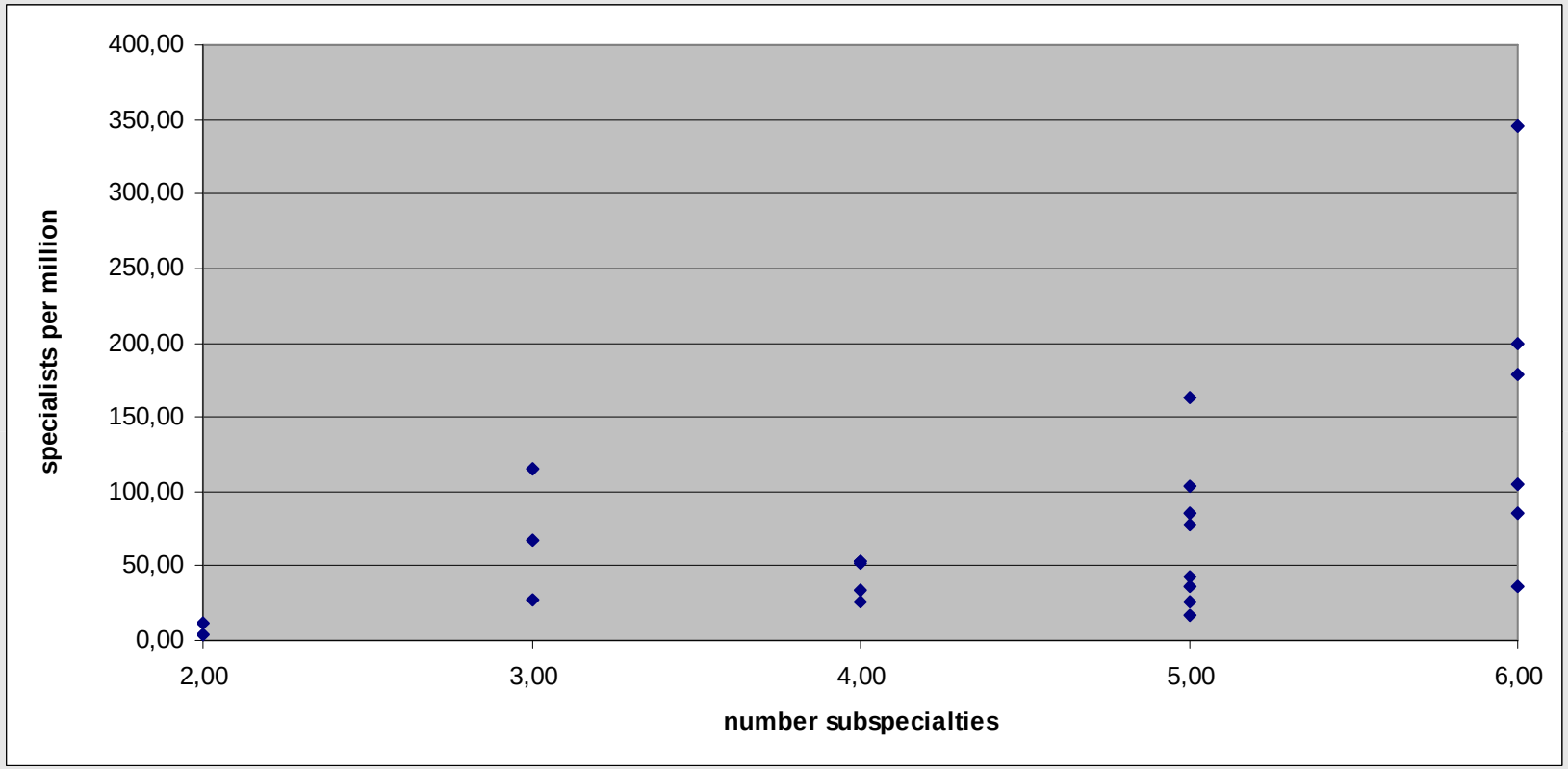


General/polyvalent =
biochemistry + hematology + microbiology

64% countries (13/24)

88% of EU laboratory specialists in “polyvalent” countries

Number of laboratory specialists relation monovalent-polyvalent



Biochemistry-hematology-endocrinology-immunology-transfusion-microbiology

Restrictions for laboratory professionals

Countries with restrictions for specialists other than MD:
Scientists: 45% (10/22)
Pharmacists: 27% (4/15)

- 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)

Clin Chem Lab Med. 2006;44(1):110-20.

EC4 European Syllabus for Post-Graduate Training in Clinical Chemistry and Laboratory Medicine: version 3 - 2005.

Zerah S, McMurray J, Bousquet B, Baum H, Beastall GH, Blaton V, Cals MJ, Duchassaing D, Gaudeau-Toussaint MF, Harmoinen A, Hoffmann H, Jansen RT, Kenny D, Kohse KP, Köller U, Gobert JG, Linget C, Lund E, Nubile G, Opp M, Pazzagli M, Pinon G, Queralto JM, Requengo H, Rizos D, Szekeres T, Vidaud M, Wallinder H; European Communities of Clinical Chemistry, EC4 Register Commission.

Laboratoire d'analyses de biologie médicale, Bagnolet, France, SFBC, EC4 Register Committee. labo93@free.fr

Abstract

The EC4 Syllabus for Postgraduate Training is the basis for the European Register of Specialists in Clinical Chemistry and Laboratory Medicine. The syllabus: Indicates the level of requirements in postgraduate training to harmonise the postgraduate education in the European Union (EU); Indicates the level of content of national training programmes to obtain adequate knowledge and experience; Is approved by all EU societies for clinical chemistry and laboratory medicine. The syllabus is not primarily meant to be a training guide, but on the basis of the overview given (common minimal

Recommended Standards for Training Specialists in Laboratory Medicine - Medical Biopathology

EC4/UEMS curriculum used?

EC4: 70% (16/23) of countries

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

UEMS “Blue Book” used in 4 countries.
- Hungary, Finland, Portugal and Slovakia
- curriculum adapted according to Swedish situation.

Duration specialist training

Scientists

2 years: 6% (1/18)
3 years: 6% (1/18)
4 years: 28% (5/18)
5 years: 50% (9/18)
>5 years: 11% (2/18)

Including pre-specialization general year (Slovenia, Finland)

- UK, Ireland: not fixed, 2 parts of 3-4 years
- No organized training (Austria, Denmark, Estonia, Romania, Sweden)
- Training only in other country (Cyprus)

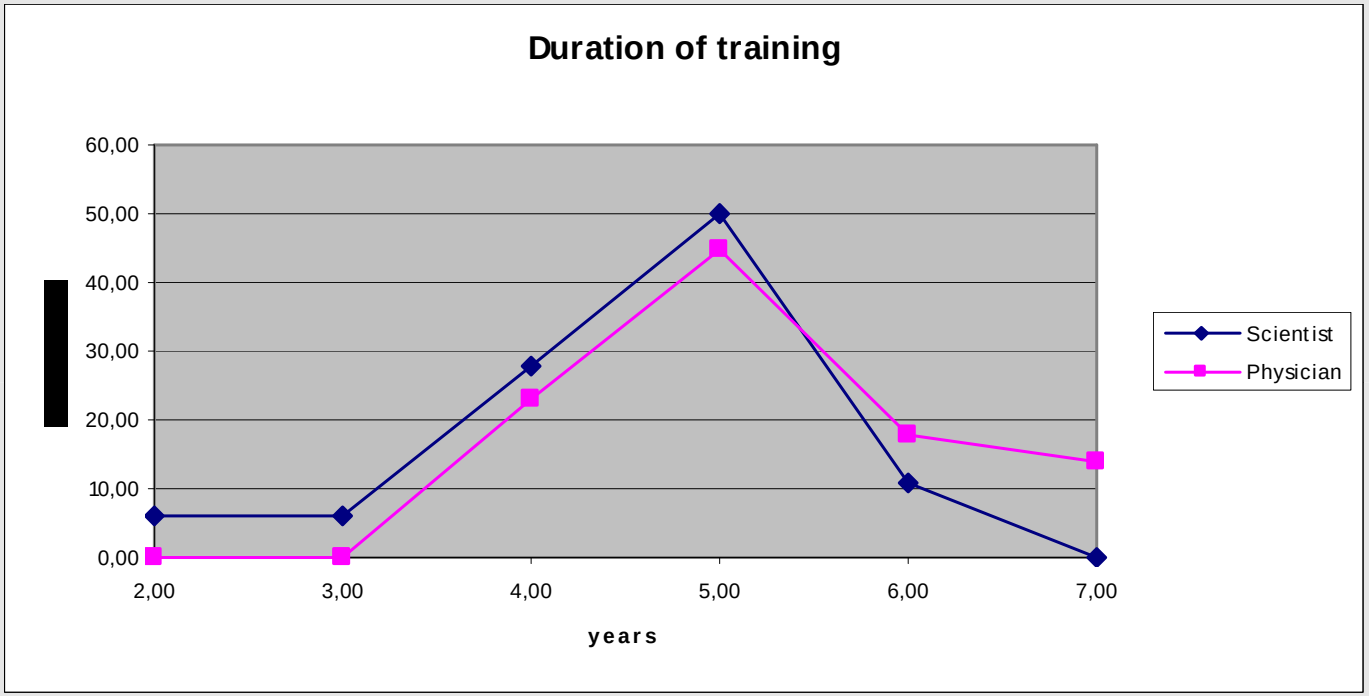
Duration specialist training

Physicians:
- 3 years: 0%
- 4 years: 23% (5/22)
- 5 years: 45% (10/22)
- 6 years: 18% (4/22)
- >6 years: 14% (3/22)

Including pre-specialization general year (Slovenia, Finland)

other:
- Netherlands: no medical specialist training of physicians since 2001
- Cyprus: no organized training (abroad)

Duration specialist training



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)

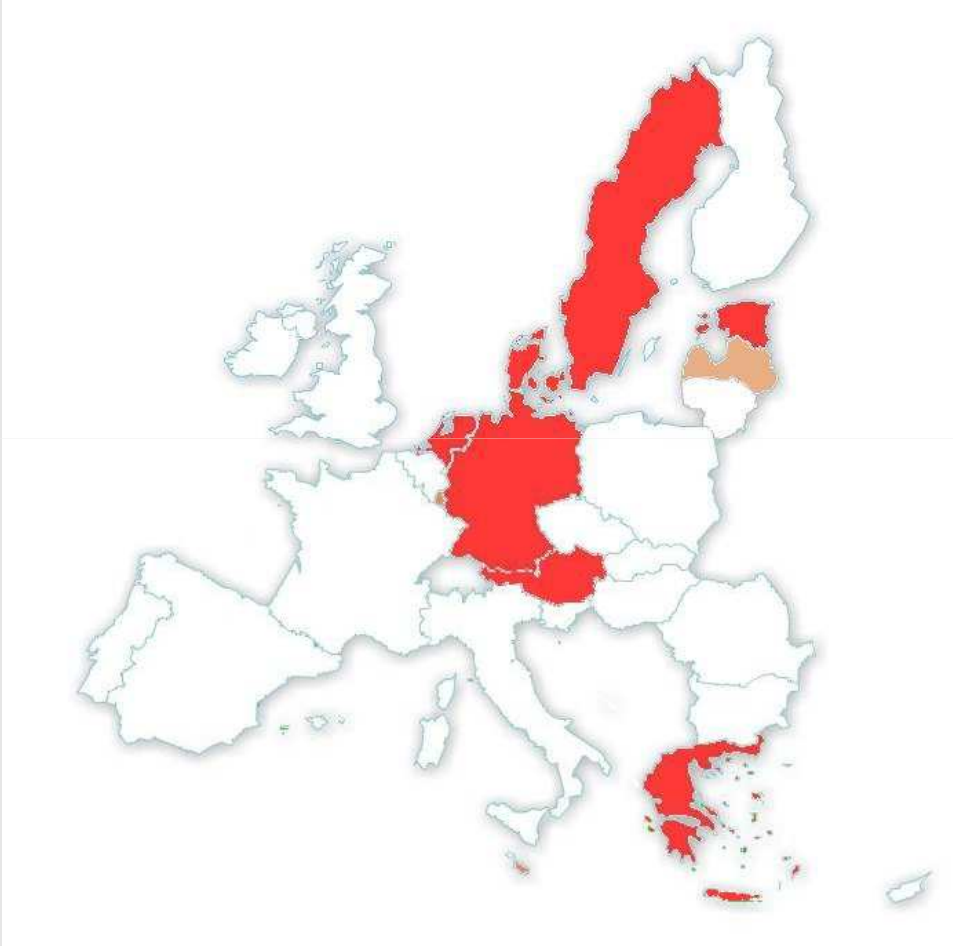
Formal recognition of laboratory specialists-scientists

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

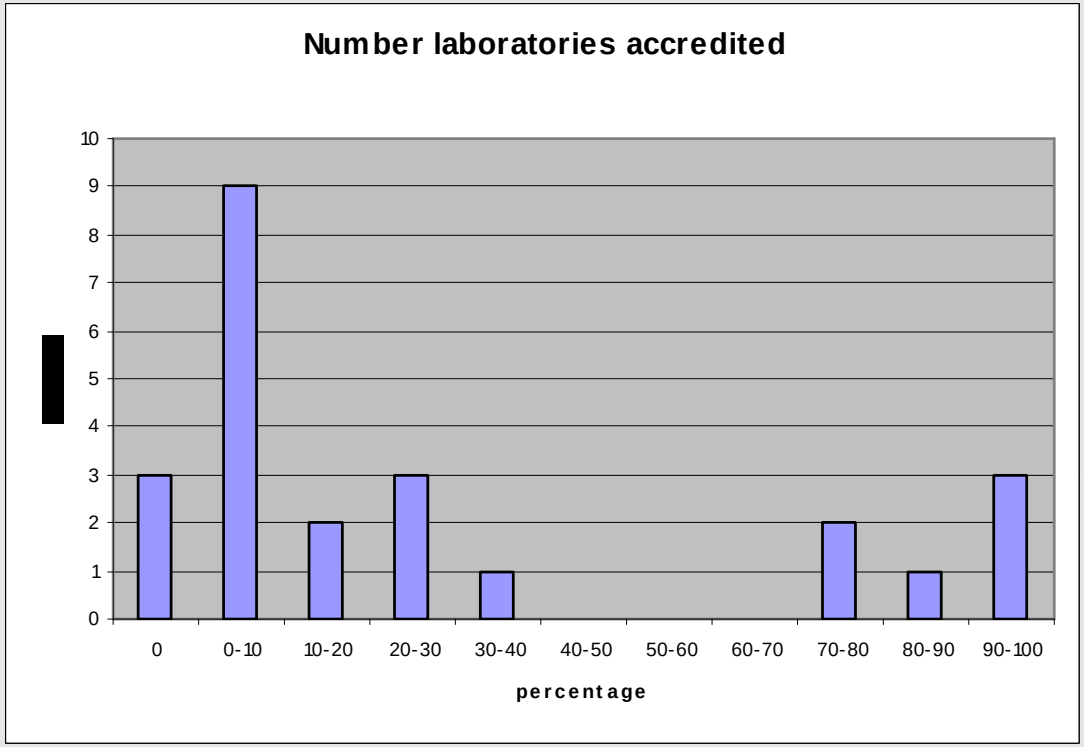
France, Belgium: no specialists, or very limited number

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

Recognition of laboratory specialists (scientists)

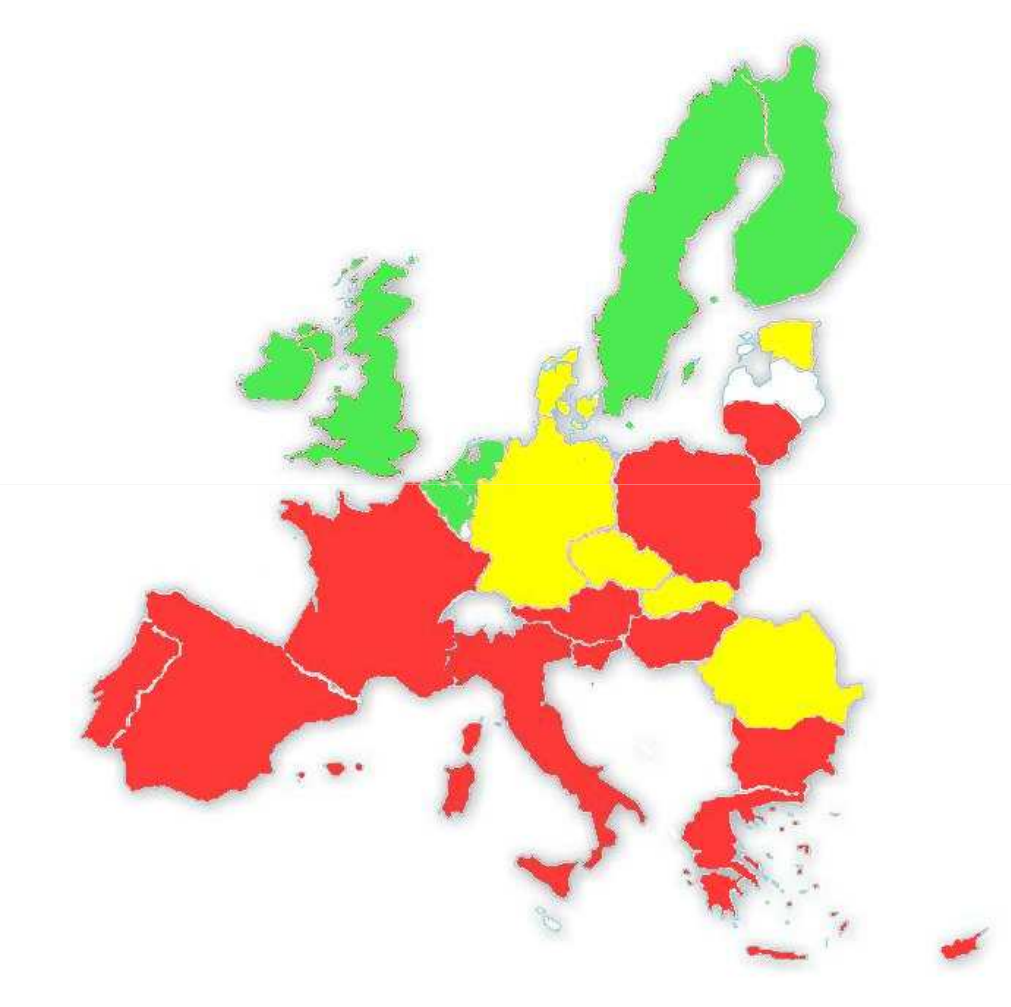


Accreditation according to ISO 15189



Low: Bulgarya, Lithuania, Slovenia
High: Netherlands, Sweden, UK

Accreditation according to ISO 15189



<10%

10-75%

>75%

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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