

JIB/ EUROMEDLAB

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**Evolution réglementaire
dans l'UE**

New legislation in the EU

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**A Directive is
proposed by the
European Commission**

to

**European Parliament
votes and Publishes
the Laws**



A Directive, European law,

shall be :

- transposed within 2 years in the National Law of all EU Member States ,after publication in the EU Official Journal.
- revised after 5 years



DIRECTIVE 2013/55/EU

17/01/2014:

Published in the EU Official Journal

17/01/2016:

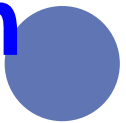
Deadline for transposition into
national Law



We have had:

- an **active participation** and a **strong involvement** in numerous meetings and questionnaires
- an **important lobbying**

from

- the “**green paper**” (June 2011)
 - to propositions of **amendments** (October 2012)
 - until now for the **Implementation**
- 

Amendements

- Discuss and take **decisions with the professionals**
- **Cooperation** of all Member States.
- **Define who are the competent authorities**
in each Member State
- **Make clear and transparent the role of the coordinators,** and the **communication** between
National Coordinators and Professional Organizations.
- **Maintain the levels of education**



Contacts points and coordinators

In each EU Member States:

1 point of contact

1 coordinator : link between the EC and MS for a Directive for all the professions concerned

In each country, **members from the ministries** concerned are nominated to work together **with the professionals, to make propositions to the EC through the coordinator.**

Now we shall work with our competent authorities at National level.



After the publication of the Directive:

11 February 2014 :Meeting in Brussels

with representatives of :

**the professionals, the governments,
members of the EP and EC.**

**20 March 2014: CEPLIS sent a letter to
Mr Martin Frohn (New Head of Unit E4 ,
DG Markt, EC)**



Then European Elections

**The new team was approached
Early 2015.**

**Meanwhile, we worked
on the new text.**

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1. Automatic Recognition (Chapter III)

Harmonisation of training requirements provides AUTOMATIC recognition of professional qualifications for

Sectoral professions :

Medical doctors, general nurses, dentists, midwives, veterinary surgeons, architects, pharmacists (but not Specialists).



2. General System (Chapters I and II)

All other professions for which

Member States require a qualification

- 800+ professions - health sector, engineers, accountants, car experts, bankers, etc...



MOST IMPORTANT ISSUES

- **European Professional Card**
- **Alert Mechanism**
- **Partial Access**
- **Language Skills**
- **Continuous Professional Development**
- **Professional Traineeships**
- **Common Training Frameworks**



Specialists in Laboratory Medecine in EU

Physicians: 13920 (40%)

Scientists: 10680 (31%)

Pharmacists: 10237 (29%)



European Professional card

The system would be based on the **existing electronic information exchange system** between Member States administrations.

‘the IMI regulation’

Internal Market Information System



Title of the Directive

DIRECTIVE 2013/55/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL...

Amending Directive 2005/36/EC on recognition of professional qualifications and regulation(EU) N° 1024/2012 on administrative cooperation through the **Internal Market Information System**

(‘the IMI regulation’)



Comments

The 7 “**sectoral**” professions have already agreed on harmonization of education. They can be **the first to experience the IMI System.**

While the **other professions agree on basis for harmonization**, the IMI system **should be ready** (by the end of transposition period)



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COMMON TRAINING FRAMEWORKS

A new regime for automatic recognition.

The new Directive makes it possible for EU Member States to decide on a common set of knowledge, skills and competences that are needed to pursue a given profession.



Proposition of CTF for Specialists in laboratory medicine

Based on the level required by the European EC4 Register, according to:

- a Syllabus,
- training requirements and
- a code of conduct.



Proposals for training requirements

- **Education + training : 10 years**

 - Academic education : minimum 4 years

 - Master's degree

 - Professional training : minimum 4 years

 - concluding in a recognised exit qualification

- **Flexibility in remaining year :**

 - extra academic study

 - extra training



For the **content**, the program is divided in **4 catégories** (the same as in the Syllabus)

Clinical Chemistry: Biochemistry, Endocrinology,
Immunochemistry, Toxicology,

- **Hematology** : Blood cells, Coagulation,
Transfusion, Cell Immunology
- **Microbiology**: Bacteriology, Virology, Mycology,
Parasitology
- **Genetics et assisted reproduction (IVF)**



Proposals for training content

- General chemistry : minimum 35%
- General chemistry + haematology :
minimum 65%
- 35% flexible : chemistry,
haematology,
microbiology,
IVF and genetics,



MEDICINE-PHARMACY-SCIENCES (5-6 Years)

**Training in
Polyvalent
clinical Biology
(4-5 Years)**

**Training in BASIC Polyvalent
Clinical Biology (1-2 years)
(3-4 years)**

- **Biochemistry**
- **Hematology**
- **Microbiology**
- **Molecular Genetics**

**EUROPEAN SPECIALISTS IN
LABORATORY MEDICINE**

2015: the European Commission is organised with new services.

_Ms Sophie Weisswange is nominated at the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs Unit D4 Free Movement of Professionals, **responsible for CTF.**

Prof. Koutroubas, Director of CEPLIS has an important meeting with her, on **13th March 2015**

She answers our questions.

Since then we know how to proceed for implementation.



The European Commission's DG for Growth has limited resources, a given budget, and has to work simultaneously on many projects.

For this reason it doesn't have the capacity to examine several CTF projects at the same time.



In this context, the
lobbying is very important.

Thanks to our relationship with **CEPLIS** and
Pr Theodoros Koutroubas, we have **very good**
contact with the European Commission.

One member of the DG Unit D4
of the European Commission, have attended
the CEPLIS General Assembly 5th June 2015



Our profession is a good candidate for CTF as:

- **Our federation represents the 28 EU Member States**
- **We have studied all together the CTF and are ready to make propositions already agreed by the professionals of the 28 MS**
- **We have organised a vote on the European name of the profession (whatever the National name): Specialist in Laboratory Medecine**
- **Our profession is the link of all medical professions. (70°/° of diagnostics, treatments follow up, prevention...)**
- **We should easily find 10 countries to make common propositions for harmonisation**



At CEPLIS, we have now a **WG on CTF**
Chair: Simone ZERAH

We have the best conditions to
progress.

Other professions are interested :
We are **learning** from each other



Some Specific questions

submitted by

CEPLIS member-organisations

to the European Commission



Question 1:

*A country in which a profession seeking a CTF does not have a common training at the national level but does have a common regulation is eligible to become one of the ten Member States needed for a CTF?
(ex: : Luxembourg, Cyprus, Malta.)*

Yes, such a country is eligible. Either the training or the profession itself, should be regulated in a Member State in order for it to be a part of a CTF.



Question 2

*The countries have to make propositions
after taking the advice of the
professionals*

Correct : it is clear in the Directive

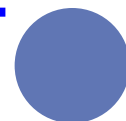


Question 3

MS that are not signatories of a CTF have the right to opt out?

It might be difficult to do so, but the Commission cannot tell for the moment, as nothing is yet tested. Obviously, **the goal of the Commission is to include as many Member States in a CTF as possible.**

Need to balance between “small” and “big” Member States when working towards a CTF




Question 4

When is the guideline document aiming at helping stakeholders to better understand CTF to be published?

As soon as possible (hopefully by Summer)

A conference could be organized following the publication of the document in question in order to give stakeholders the chance to ask their questions directly.



Question 5

What is the process to obtain a CTF for a profession?

First act at National level to be sure to have at least 10 countries.(countries not yet ready can participate to discussions)

At the same time, find an agreement (Professionals + Member States) on the level required.



Question 6

As the Directive shall be transposed by January 2016, what is the deadline to obtain a CTF for a profession?

No limits at the moment , as the European Commission will begin to consider the propositions after the transposition of the Directive.



CONCLUSION

How preparing and implementing a CTF

1°) At national level:

- All the representatives of the profession shall contact and collaborate at national level with the **ministries in charge of the transposition.**
(French Example)

- Prepare in each country, for each profession, **harmonization** according to **CTF** propositions

2°) At European Level:

Governments + Professionals agrees to make propositions to the EC

Find 10 countries :
agrees on common propositions



Directive 2005

Directive 2014

1) 7 sectorial professions:
Automatic recognition
= free movement

No change

2) General System

Common-Platforms (all MS)

Common –training Frameworks(10 MS)

Automatic recognition=
free movement

Predefined
compensation measures

Harmonisation




After that stage, we will work on the
Professional cards:

We will benefit from the experience
of the 'Sectoral' professions.

■





Thank You

