Ordre National des Médecins
Conseil National de l'Ordre

BUNDESÄRZTEKAMMER

General Medical Council

15 October 2010

Dear Mrs Fröhlinger

National experience reports for doctors and Berlin statement

Further to your letter sent in April 2010 and our initial response on 23 September, we are writing to inform you about the outcome of the informal network of European competent authorities responsible for the recognition of medical qualifications. We are pleased to report that to date 22 national experience reports[1] on the implementation of Directive 2005/36/EC on the mutual recognition of professional qualifications have been submitted to the European Commission by the network.

As you recall, in March 2010, the Bundesärztekammer, the Conseil National de l'Ordre des Médecins, and the General Medical Council (UK), were supported by the European Commission in coordinating an informal network of competent authorities responsible for the recognition of medical qualifications. The aim of the group was to discuss the implementation of the Directive in the EEA countries and aid the preparation of national implementation reports.

Over the past few months 28 competent authorities from 23 EEA countries held constructive plenary discussions in Paris (7 May), London (2 July) and Berlin (13 September). The meetings benefited from the European Commission's input as an observer and provided participants with an opportunity to suggest changes and clarifications to the questionnaire proposed by the Commission, share best practises, and experiences, and debate common concerns.

To facilitate discussion, the network coordinators set up a secure online platform, which served as a repository of information and helped competent authorities share their draft national reports. The platform was met with broad enthusiasm and competent authorities agreed to consider this tool in the future.

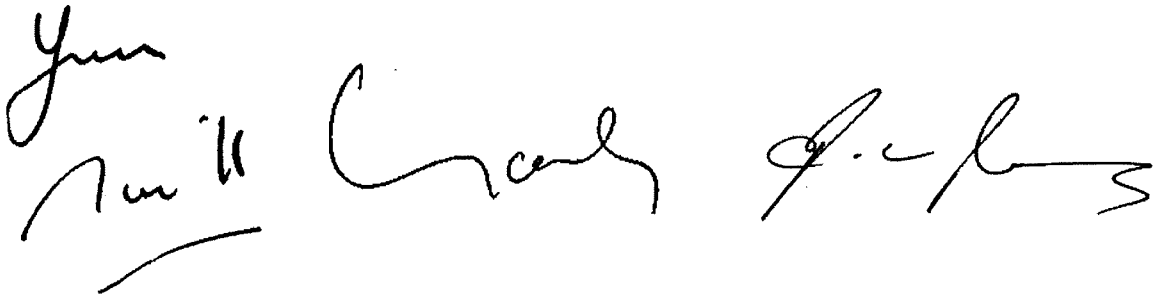
Overall the network agreed that the system of automatic recognition has facilitated the mobility of doctors and has agreed to continue to meet in the future, on an informal basis, to improve collaboration and understanding of medical education and training systems and recognition procedures across Europe.

[1] The following countries have responded to the European Commission questionnaire: Austria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Latvia, Luxemburg, Malta, The Netherlands, Norway, Poland, Portugal, Slovenia, Spain, Sweden, and the UK.

In the course of their deliberations, competent authorities have also identified parts of the legal framework that could benefit from further examination and clarification. In this context, the network discussed and agreed a joint statement, calling on the revision of the Directive to focus on areas that will support doctor mobility and cooperation amongst competent authorities while, at the same time, ensure that patient safety in Europe is not compromised. We are very pleased to report that to date 25 competent authorities from 23 EEA countries have officially endorsed the Berlin statement and we would like to bring this to your attention. We hope that the content of the statement will be considered by the Commission in its revision of the Directive.

We would like to thank the European Commission for their positive and constructive engagement with competent authorities over the past few months and look forward to receive feedback from discussions held at the Group of Coordinators meeting held on 27 September and to contributing further to the evaluation and revision of the Directive in the coming months.

Yours sincerely



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General Medical Council	**Conseil national de l'Ordre des médecins**	**Bundesärztekammer**

cc. Jürgen Tiedje, An Baeyens

Berlin Statement
13 September 2010

European Commission's evaluation of Directive 2005/36/EC on the mutual recognition of professional qualifications

Since May 2010 the informal network of competent authorities for the recognition of professional qualifications for doctors has held a series of meetings to discuss and share their experiences with the implementation of Directive 2005/36/EC on the mutual recognition of professional qualifications.

The network has brought together 28 competent authorities from 23 member states to stimulate discussions and support the drafting of national experience reports on the Directive.

The network agrees that the system of automatic recognition provided by Directive 2005/36/EC has proven successful in facilitating the recognition of medical qualifications within the European Economic Area.

The network has also shown that with a high level of doctor mobility around Europe, competent authorities are keen to work cooperatively and collaboratively to contribute to safe healthcare in Europe, and declare their intention to continue their collaboration within the structures of the informal network. To enhance transparency within the recognition of professional qualifications competent authorities intend to work together voluntarily to create a repository of detailed information on the content of medical training for each specialty. This may include historical information of titles and name of documents.

Competent authorities see the Commission's current evaluation of Directive 2005/36/EC as a valuable opportunity to highlight a number of areas that would benefit from further examination to ensure that professional mobility is maintained and to enhance patient safety. We would like to express our appreciation of the open and co-operative approach undertaken by the Commission in the course of the evaluation process.

Further to our meetings and the exchange of experiences in relation to the evaluation of the Directive we call on the Commission to:

- Continue to facilitate the identification of competent authorities responsible for the recognition of qualifications for doctors; require competent authorities to be listed on the Internal Market Information system (IMI); oblige competent authorities to respond to all queries in an appropriate timeframe regardless of whether they are sent through IMI or through other means; develop and improve IMI to allow competent authorities to carry out primary source verification of documents.

- Examine in cooperation with the Competent Authorities appropriate competence assurance mechanisms (e.g. CPD/CME, revalidation, etc.) for doctors. This will enhance trust in the recognition of professional qualifications and ensure patient safety by allowing competent authorities to assure themselves that the doctors they register have kept their skills and competence up to date since the award of their medical qualifications.

- Consider including the Certificate of Current Professional Status / Certificate of Good Standing to the documents listed in Annex VII.

- Explore mechanisms, such as the alert mechanism provided for by the Services Directive, that will improve the exchange of information about doctors that has a bearing on patient safety in Europe and on professional competence. Facilitate the identification of competent authorities responsible for taking regulatory action against doctors[1] to ensure that only those doctors that are fit and safe to practise avail themselves of the benefits of freedom of movement within the EEA.

- Ensure that there is legal clarity about regulatory responsibility in instances of cross-border provision of services. This should also be considered in the light of developments in the field of telemedicine and remote diagnosis, where neither the patient nor the doctor physically moves.

- Provide clarification about the term 'temporary and occasional'; support competent authorities in developing a common framework that will assist them in dealing with recognition in cases of subsequent applications for temporary and occasional provision of services (e.g. seasonal mobility).

- Examine the language provisions in the Directive to address the concerns of competent authorities in relation to language proficiency of migrant doctors in the interest of patient safety.

- Examine within the course of the revision of the Directive the increasing occurrences of false documents and fraud and find means of combating these effectively.

Further information and concrete case studies and examples in support of this statement are contained in the national experience reports submitted by competent authorities to the European Commission in September 2010.

[1] For example, the removal of a licence to practise.

Competent authorities in support of the Berlin statement

Austria	Österreichische Ärztekammer
Cyprus	ΙΑΤΡΙΚΟ ΣΥΜΒΟΥΛΙΟ ΚΥΠΡΟΥ
Czech Republic	Ministerstvo zdravotnictví
Denmark	Sundhedsstyrelsen
Estonia	Tervisemet
Finland	Sosiaali- ja terveysalan lupa- ja valvontavirasto, Valvira
France	Conseil National de l'Ordre de Médecins Ministère de la Santé
Germany	Bundesärztekammer
Hungary	Egészségügyi Engedélyezési és Közigazgatási Hivatal
Ireland	Medical Council
Italy	Ministero del lavoro, della salute e delle politiche sociali
Latvia	Latvijas Ārstu biedrība
Lithuania	Sveikatos apsaugos ministerija
Luxembourg	Ministère de la Santé
Malta	Kunsill Mediku
The Netherlands	Koninklijke Nederlandsche Maatschappij tot bevordering der Geneeskunst Ministerie van Volksgezondheid Welzijn en Sport - BIG register
Norway	Statens autorisasjonskontor for helsepersonell
Portugal	Ordem dos Médicos
Romania	Colegiul Medicilor din Romania
Slovenia	Ministrstvo za zdravje
Spain	Ministerio de Sanidad y Política Social
Sweden	Socialstyrelsen
UK	General Medical Council

Nursing & Midwifery Council

EU National reports

on the implementation of Directive 2005/36/EC for the profession of nursing

17 September 2010

Background information

Directive 2005/36/EC on the recognition of professional qualifications came into force in October 2007. The aim of this directive is to facilitate the free movement of workers across the EU by establishing rules on the mutual recognition of professional qualifications. It brings together 15 directives to create a single piece of legislation on the mutual recognition of professional qualification.

Like most directives, Directive 2005/36/EC has to be reviewed by the EU Commission five years after its transposition. To this end, the EU Commission has begun its consultation on the review in the spring of 2010 with a view to have recommendations for amendments by 2012. For the sectoral professions, the EU Commission decided to involve national competent authorities for each profession in the running of the consultation. Competent authorities are named by governments as the authority responsible for the recognition of professional qualifications for individual professions.

In this context the Nursing and Midwifery Council of the United Kingdom was asked by the EU Commission to coordinate the collection of national reports on the implementation of the directive for the profession of nursing. The following is a report on the consultation process ran by the Nursing and Midwifery Council.

Methodology

The consultation exercise was structured around a common questionnaire, three meetings of EU competent authorities for nursing and information sharing through a web-based platform.

The common questionnaire was first drafted by the EU Commission and then amended by the EU competent authorities for nursing to give them the opportunity to highlight concerns that are specific to the profession. Competent authorities met three times in plenary sessions;

1. **London meeting 25 May 2010**: the NMC hosted the first meeting involving EU regulators for nursing in order to begin the first phase of the review of the EU directive on professional qualifications. Despite the short notice in seeking to organise the first meeting, competent authorities from 16 member states (Austria, Belgium, Denmark, Estonia, Spain, Finland, France, Hungary, Ireland, Luxemburg, Malta, Poland, Portugal, Sweden, Slovenia, United Kingdom) were present, together with representatives from the Internal Market Directorate of the Commission. The group of competent authorities worked on a list of questions which became a questionnaire for national reports on the implementation of Directive 2005/36.

2. **Brussels meeting 22 June 2010**: the EU Commission hosted the second meeting. 20 member states participated (Austria, Belgium, Cyprus, Denmark, Estonia, France, Germany, Hungary, Ireland, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom). Competent authorities from seven countries gave presentations on their national views on specific areas of the directive. The EU Commission gave a presentation on the IMI system. This presentation provided an opportunity for countries to raise concerns around sharing information cross-border on fitness to practise. Many competent authorities supported change in the law to allow exchange of information through an alert system which could be incorporated into the IMI system. The NMC agreed to set up an online platform where all competent authorities for nursing would be able to view each other's national reports and exchange views on them between July and August.

3. **Madrid meeting 7 September 2010**: The Spanish Ministry of Health hosted the third and last meeting of competent authorities. 14 member states participated (Austria, Belgium, Cyprus, Czech Rep., Denmark, Spain, Estonia, France, Germany, Hungary, Ireland, Portugal, Slovenia, UK). Competent authorities from four countries gave presentations on their national views on specific areas of the directive. Participants discussed the next steps in the process of the review of the directive and agreed on future collaboration.

Between the meetings competent authorities worked on their national reports, liaising with their national stakeholders and sharing information with other competent authorities. In order to streamline this process an online platform was created and administered by the NMC. This helped competent authorities share their draft national reports, synchronise calendars and share tasks. The online platform was also used to initiate exchanges of ideas on such issues as the care of older people and the structure of nursing education in EU countries. This platform was met with general enthusiasm and it was agreed that the group of competent authorities would continue using this tool in the future.

Using all submitted final reports the NMC undertook to summarize the results and highlight common issues. These are described in the next section of this paper.

Next steps

The collection of national reports on the implementation of Directive 2005/36/EC constitutes only the first part of the consultation exercise. It was designed to evaluate how the directive works in practice in each member state. The second phase will be a consultation aiming at collecting recommendations for amendments. In this context it is important that competent authorities for nursing continue to collaborate and share their desired amendments with the EU Commission.

This view was shared by all competent authorities for nursing. They have agreed to continue their collaboration within the informal network with the help of the online platform and future meetings. It was agreed that competent authorities would meet in the spring of 2011 to discuss the following important themes that were identified in their national reports: minimum standards for education, language testing, continuous professional development and aptitude tests.

Recommendations

Further work

Competent authorities for nursing have come to the agreement that further work needs to be done and suggestions for amendments should be made concerning:

1. Minimum training requirements
   The minimum training requirements provided for in the directive date back three decades. They need to be updated to recognise that nurses should be prepared for new roles and broader responsibilities and to mirror scientific and academic progress.

2. Language testing
   The directive prevents competent authorities from systematically language testing migrating nurses who apply for registration in their country. There is general consensus that this situation puts patients at risk and the directive should be amended to give competent authorities more powers in this matter.

3. Continuous professional development (CPD)
   Competent authorities generally agreed that CPD should be made compulsory in the directive. A harmonized definition for it should be established as it would help harmonize the profession across the EU.

Cooperation between competent authorities

There has been widespread support for the continuation and evolution of the network of competent authorities for nursing that has evolved as a result of the first stage of the review. This future cooperation should focus on developing the following areas:

1. Administrative cooperation. Contacts between competent authorities help create trust which eases the recognition procedure for migrating nurses. It also helps authorities identify fraud, thus enhancing patient safety.

2. Subject specific meetings. Most competent authorities share the same practical issues in implementing the directive with varying levels of resources. Meeting on a bi-annual basis to discuss common issues and share best practice will help competent authorities perform their duties under the provisions of the directive.

Administrative tools

4. Internal Market Information System (IMI)
   There is a clear recognition that it is a very good system. Competent authorities agreed that it would be very useful to insert an alert mechanism as is the case for the professions of the "services directive".

5. Professional Cards
   There is careful interest in the advantages that a professional card could bring. It could help streamline the process of registration and facilitate mobility. It is to be noted that in order to combat fraud potential professional cards must be issued by competent authorities and not professional associations. The card should be a uniform system for the whole of the EU and there needs to be complete interoperability between the IT systems of competent authorities. One way of achieving this, rather than creating new systems, would be to link professional cards to the trusted IMI system.

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Themes emerging from the national implementation reports

1 25 EU member states and Norway have submitted their national reports. The following is a summary of answers structured along the main themes of the questionnaire. This summary highlights main common trends and specifies differences where they are notable.

A. Recognition procedure

2 Online applications:

2.1 Six countries (DE, ES, HU, RO, SE, SL) accept email/online applications; however, all documents and certificates need to be posted. A few other countries have application forms which can be downloaded from their websites but all documents submitted must be in paper.

3 Automatic recognition:

3.1 The majority of competent authorities (CA) agree that this system is straightforward, fast and easy. It's mostly seen as a successful system. However, some CAs find that it hides differences in education and scope of practice. They also find it difficult to match foreign trainings with national subcategories of nursing when they cannot look at transcripts of training. The issue of the impossibility to language test is also a concern.

4 Acquired rights:

4.1 Although this system is recognised as fast for the applicant, CAs have many issues with it. First of all they do not know whether the required amount of recent professional experience (three out of five years) should be full time or part time. CAs believe that in any case, professional experience is not sufficient to compensate for a lack of training. There are also issues on documents submitted by these applicants; they often find it difficult to prove their professional experience and CAs have expressed doubts as to the reliability of the information on their fitness to practise. CAs are calling for a clear definition of "effective and lawful practice" as mentioned in the directive.

5 General system

5.1 CAs recognise that this system is more time consuming and that it is often difficult to obtain transcripts of training. However, this system is deemed safer for patients as it allows the CAs to have more detailed information on the training of the applicant.

6 Current notification system

6.1 Not many CAs have views on this tool. A few find it good.

7 Use of the general system

7.1 19 countries use the general system (AT, BG, CY, CZ, DE, DK, ES, FI, FR, HU, IE, LV, MT, NL, NO, PT, RO, SE, UK)

7.2 2 countries don't (BE, EE)

8 Adaptation periods/aptitude tests

8.1 Nine countries have a form of aptitude test (CZ, DK, EE, ES, FI, FR, NL, NO, RO) although in most cases they are done on an ad-hoc basis

8.2 Applicants often find it difficult to undergo adaptations or tests because they do not have sufficient knowledge of the national language. Some adaptation periods are very long. CAs have highlighted the issue of who should fund these measures.

9 Third country trained applicants who have been recognized in another EU country

9.1 This happens very rarely and no major issue have been mentioned except for the difficulty to obtain the right documents in certain case

10 Structure of the competent authority

10.1 In 15 countries the CA is a department of a ministry (AT, BE, BG, CY, CZ, DK, EE, ES, LT, LV, LU, NL, PL, SE, SL)

10.2 In 2 countries it is shared between an Order and a ministry (FR, RO)

10.3 In 4 countries it is an independent body under a ministry (FI, HU, MT, NO)

10.4 In 3 countries it is an independent body (IE, PT, UK)

10.5 In Germany it is a combination of systems

B. Temporary mobility

11 Temporary provision of services

11.1 This has hardly ever been used. Only Spain had one case.

12 Interpretation of "legal establishment in home member state"

12.1 To most CAs this means that the applicant is legally entitled to practise in their home country and that they do not have any sanctions on them. It is also interpreted as meaning that the applicant has a valid registration in their home country.

13 Interpretation of "temporary and occasional"

13.1 Most CAs found this provision difficult to interpret. Some did so on a case by case basis, others limit the duration of practice to three months. France is of the view that CAs should be allowed to ask for evidence of the temporary and occasional nature of the service.

14 Necessity of the "prior declaration" system

14.1 Most CAs agreed that this system is very important in order to protect patients. They noted that it should be kept as it is essential to be able to supervise the service providers and to run background checks on them. The system replaces the application for recognition and specifies the temporary nature of the service.

14.2 Some CAs expressed their concern that most professionals do not know about this system.

14.3 There is agreement that the system should be made compulsory and be made a specific requirement in the directive. Maybe IMI should be used for it.

C. Minimum Training

15 Common minimum training requirements

15.1 Although some CAs did not have any issue with the minimum training requirements, other highlighted the fact that they hadn't changed since 1977. There is thus a need to update the wording and the requirements to recognise that nurses should be prepared for new roles and broader responsibilities.

15.2 The requirements should be changed in order to reflect the fact that nursing is becoming evidence based and to be in accordance with the Bologna process. Also, a few CAs noted that it is not in line with scientific progress and that the separation of theory and practice is not helpful in light of modern training.

16 Mutual trust between member states

16.1 Although most CAs agree that they trust their counterparts and that personal meetings contribute greatly to building trust there are a few issues on an individual basis.

16.2 The fact that the directive is not uniformly understood and implemented does create some communications issues between all CAs as to their interpretation of legislation.

17 Continuous professional development (CPD)

17.1 CPD is mandatory in 18 countries (AT, BG, CZ, EE, ES, FI, FR, HU, LT, LUX, LV, NL, POL, PT, RO, SE, SL, UK)

17.2 CAs generally agreed that CPD should be made compulsory in the directive. One CA thinks that CPD should be recognised across the EU and that a harmonized definition for it be established.

D. Administrative cooperation

18 Simplification of procedures thanks to cooperation

18.1 CAs agree that administrative cooperation helps the procedures. Certainly this is the case when the applicant doesn't provide all the necessary documents.

18.2 Meetings with other CAs' staff are very important as it helps develop trust and understanding of individual CA's circumstances.

18.3 It was noted that this cooperation is easier if there is only one CA per country.

19 IMI

19.1 All countries were registered with IMI

19.2 Although for a majority of CAs, IMI has not been used often, there is a clear recognition that it is a very good system.

19.3 Areas which could be improved are: the interface; the predefined questions; translation into more languages; insert an alert mechanism

20 Professional Cards

20.1 Most CAs were carefully interested in the advantages that a professional card could bring. It was felt that it could help streamline the process of registration and facilitate mobility, although some CAs were adamant that some documents should always be submitted in paper form.

20.2 Most CAs noted that such a professional card must be issued by CAs.

20.3 Europass CV could be one of the pieces of information which the card give access to.

20.4 The card should be a uniform system for the whole of the EU and there needs to be complete interoperability between IT systems.

21 Exchange of disciplinary and fitness to practise (FTP) information

21.1 There is a wide variety of approaches to this;

21.2 Some CAs exchange on a case by case basis; other have information on their website and the Nordic countries have their own system.

21.3 Some CAs noted that they were legally not allowed to share information proactively.

21.4 Many CAs thought that the IMI alert mechanism should be extended to the sectoral professions.

21.5 Two CAs called for a EU central register of disciplinary and fitness to practise sanctions.

E. Other observations

22 Language testing

22.1 In most countries this was done at the time of employment.

22.2 Some CAs language test applicants at the time of registration.

22.3 One CA tests nurses six months after their registration.

22.4 In one country, registration is not sufficient; applicants must then obtain a permit to practise which is conditional to adequate language skills.

23 Evidence of complaints about insufficient language skills

23.1 13 CAs have received complaints (AT, CY, DK, DE, IE, LU, MT, NL, NO, PL, SE, UK)

24 Fee for recognition of qualification (not registration fee)

AT = 140€	BE = 0	BG = 133€	CZ = 80€
DK = 0	EE = 190€	ES = 0	FI = 300€
FR = 0	DE = var.	HU = 200€	IE = 200€
LU = 0	LT = 0	LV = 56€	NL = 0
NO = 124€	PL = 0	PT = 0	RO = 0
SE = 0	SL = 17€	UK = 0	

25 Interpretation of Art. 11

25.1 There are different understandings of the application of article 11.

25.2 2 CAs believe it does not apply to nursing.

25.3 Several CAs understand it to apply where automatic recognition doesn't apply.

25.4 Some CAs have issues with other CAs saying that applicants meet the directive when it isn't true.

25.5 In general there is dissatisfaction about each other's different understanding of the article.

Network of European Midwifery Regulators

Evaluating the Professional Qualifications Directive
National Experience Reports for the midwifery profession

Introductory paper

- **Context**

An assessment exercise of the implementation of Directive 2005/36/EC was officially launched by the European Commission in spring 2010 in order to feed into the review of the directive planned for 2012. The EU Commission needs to evaluate how the directive works in practice; it is therefore reaching out to its stakeholders and in particular to Competent Authorities in charge of the sectorial professions.
The expected output of this process is to get National Experience Reports for all EU Member States. These reports will be made public in the middle of September 2010.

The Network of European Midwifery Regulators[1], and the Conseil National de l'Ordre des sages-femmes was tasked by the EU Commission to collect National Experience Reports from different EU countries.

- **Methodology**

A meeting with midwifery regulators and competent authorities was organised in Brussels on 21 June to discuss the questionnaire prepared by the Commission and debate about common issues[2].
The questionnaire was circulated at the end of June and contributions received from the end of August. Additional work and follow up was coordinated by the Policy Working Group of the Network[3] that met in Paris on 30 August and prepared this common introductory paper. Moreover, information exchange took place through emails and the Network's website

[1] Launched early 2009 by a joint initiative of the French Chamber of Midwives (Ordre National des sages-femmes) and the Nursing and Midwifery Council (UK), the Network is an informal forum of cooperation which groups the regulators and competent authorities of the midwifery profession in European countries. The aim of such a network is to improve the mutual understanding and exchange of best practices between regulators and competent authorities and to co-ordinate joint communications with EU decision makers on issues of mutual concern, especially in regard to EU legislation.

[2] More information about this meeting :
http://www.nemir.eu/index.php?option=com_content&view=article&id=16%3Asummit-21-june-2010-brussels&catid=6%3Asummits&Itemid=3

[3] The policy working group of the Network of European Midwifery Regulators brings together representatives from midwifery Competent Authorities from: Italy, Norway, Portugal, Malta, Hungary, France, United Kingdom and Ireland

(www.nemir.eu), where collected reports were posted and made available to other midwifery Competent Authorities.

- **Next steps**

Cooperation between Midwifery Competent Authorities and regulators in the framework of the informal Network has already proven to be an efficient way to create trust, identify best practices and understand each other procedures which contributes to facilitate recognition processes. This will go on throughout 2010 and 2011 with a focus on concrete recommendations for amendments to Directive 2005/36/EC. A **plenary meeting (Summit) of the Network will be organised during the first semester 2011** and be dedicated to the following up of the evaluation process.

- **Respondents**

1. Austria : Österreichisches Hebammengremium
2. Bulgaria: Ministry of Health
3. Cyprus: Cyprus Nursing and Midwifery Council
4. Czech Republic: Health Ministry
5. Estonia: Health Care Board
6. Denmark: Sundhedsstyrelsen
7. Finland : National Supervisory Authority for Welfare and Health (Valvira)
8. France: French Midwives Chamber (Conseil National de l'Ordre des sages-femmes) & Ministry of Health
9. Germany: Freie Hansestadt Bremen Senatorin für Arbeit, Frauen, Gesundheit, Jugend und Soziales - English Version
10. Hungary: Office of Health Authorisation and Administrative Procedures
11. Ireland : An Bord Altranais
12. Latvia : Health Inspectorate
13. Lithuania: Ministry of Health and Ministry of Education and Professional Training
14. Luxemburg: Ministère de la santé
15. Malta: Council for nurses and midwives
16. Netherlands: Ministry of Health, Welfare and Sport (Central Information point Professions in Health Care)
17. Norway: the Norwegian registration Authority for Health Personnel
18. Poland: Ministry of Health
19. Portugal: Ordem dos Enfermeiros
20. Romania: Order of Nurses, Midwives and Medical Assistants in Romania
21. Slovenia: Ministry of Health
22. Spain: Ministry of Health and Social Policy
23. Sweden: National Board of Health and Welfare (Socialstyrelsen)
24. United Kingdom: The Nursing and Midwifery Council

- **Summary of common observations**

The Competent Authorities (CA) and regulators for midwifery in the EU/EEA welcome the EU Commission's consultation on the review of Directive 2005/36/EC. The Directive on the mutual recognition of professional qualifications has enabled European midwives additional freedom of movement in the EU and has positively encouraged cooperation between Competent Authorities. However, respondents globally raise the need for better balance between free movement objectives, the safety of mothers and babies and quality of professionals.

The following is an analysis of common observations of the implementation of the Directive in EU/EEA countries (questions numbers are similar to the questionnaire's ones).

A. **Recognition procedure in case of migration on a permanent basis**

1. The majority of countries do **not accept applications by email.** Often applications form can be downloaded, but supportive documentation (certified copies) must be submitted by post.

2. Statistics. The numbers of migrating midwives from the EU has globally increased since 2000 but this does not seem to be a quantitatively large phenomenon. Information about the country of origin would have been useful to collect. It seems that migrating midwives are mostly **coming from neighbouring countries or culturally close countries.** Commonality of language plays a role in this respect (Ex.: UK/Ireland, Belgium/France, Greece/Cyprus). Midwives' mobility also appears to be an **unbalanced phenomenon.** Migrating midwives are coming from a small number of EU countries and a minority of "privileged" destination countries are actually concerned with cases of recognition of qualifications. Activities of employment agency can also have an impact on the movements that can also change depending on the economic situation in the targeted countries.

3. Views on the automatic recognition and the general system

   i. The automatic recognition system generally **works well.** It is considered by several CAs as efficient, time and cost saving. The provision of certificates of conformity for diplomas facilitates the recognition process.
   Specific problems reported:
   - Cases of **incorrect certificates of conformity** are reported (ex. documentation stating that the training met the minimal

requirements before the reference date but transcript of training shows shortfalls).

- Large **differences in the length and content of midwifery training in the EU as well as in the scope of practice**. This very low harmonisation for midwives can make it difficult for migrant midwives to access the job market smoothly and to ensure quality of care and safety of women and babies in the hosting country. It is suggested by some to introduce different levels of training and competences.
- Problem of **training programmes that do not actually meet the Directive requirements** even if they are considered to do so. Many CAs regret that there is no monitoring of compliance of these requirements for the programmes and activities of midwives.
- **No practice requirements** in the directive: people who have a compliant education programme will get authorisation to practice even if they have never practiced.

ii. Acquired rights recognition appears to be more problematic. It heavily relies on mutual trust between competent authorities.

- Difficulty to precisely **assess the length of the working experience**: what about part-time workers or applicants who came through maternity or long sick leave? For more clarity, the length should be expressed in hours.
- Theoretically, CAs must accept training programmes as low as 1 year in length via this route. This is far below the requirements for the automatic recognition.
- **False or incorrect certificates of acquired rights** are reported by several countries (ex. Certificates mentioning that the applicant was working in the origin country when it is known that he/she was already living in the host country)
- It seems to CAs very difficult to interpret "effective and lawful practice".

iii. Application of the General System differs a lot according to the Member State. Some Competent Authorities welcome the possibility offered by the General System to examine the training requirements into details and consider it as safer. Others claim this is a long and costly system. Although the General System was introduced to serve a minority of cases, it has become in some countries a significant route to registration.

4. All CAs declare to always apply the General System when automatic recognition criteria not met. Specific problems reported:
    - **Difficulty getting transcripts.**
    - **Difficulty to assess some applicant's training programmes,** in particular their clinical components or maternity care content using the transcripts of training supplied (sometimes very little input on maternity care). Specific difficulty is also mentioned with the Cyrillic alphabet.
    - The majority of countries give the choice to the migrant midwife between an aptitude test and a period of adaptation, but some do not.
    - In the case of adaptation period, some Member States have **difficulties in finding a place in medical establishments.** This is sometimes due to an insufficient language level. Cases are reported of failed or interrupted adaptation period because of professional incompetence.

5. Respondents have very **limited experience with the recognition procedure for EU citizen with professional qualification obtained in a 3rd country** already recognised in a Member State
    i. The 3 years work experience condition seems to be very open: the 3 years are not out of the last 5 years as it is for the acquired rights system
    ii. Some CAs wonder what to do in case of recognition improperly granted by the first EU Member State?

6. The recognition procedures for midwives appear to be managed by **three kinds of authorities**:
    - Autonomous regulatory bodies in charge of midwives (Councils, Ordres, Ordem, Kammer...). In some cases, professional associations have also regulatory functions.
    - Governmental bodies in charge of the regulation and supervision of health professions
    - Ministries (health, education, labour) or regional authorities

Sometimes many authorities are involved in the procedure, depending on whether the automatic recognition or general system is applied. Many CAs say it is practically **difficult to implement the directive when there is not one clearly identified authority for the recognition process but several ones.**

B. **Temporary mobility**

7. Responding CAs report very few registrations for temporary provision of services. Some Competent Authorities have reasons to believe that temporary mobility is a growing phenomenon but that **providers do not always comply with the obligation of prior declaration.**

8. The majority of respondents consider the criteria **"temporary and occasional basis" very unclear**.

9. A **prior declaration system is considered to be essential** to CAs to be in a position to check his/her qualifications (article 7. 4) and to control the fitness to practise of a midwife who provides temporary services in their country.

C. **Minimum training requirements**

10. A majority of respondents consider that the **minimum training requirements for midwives need to be updated and to be more focused on competencies and skills**. The content of the annex needs to be revised; **midwifery regulators and CAs want to be part in that process.** With midwifery educators, midwifery regulators and competent authorities have the expertise about the suitable components of midwifery training.

    I. Communication and social skills, research, evidence based practice, midwifery led care, normal birth and labour, breastfeeding, medicine management, informed consent/choice, are some of the subjects that are already suggested by CAs.
    II. **Duration of training should be also expressed in hours.**
    III. The entrance to the programme should be at 12 years minimal or the equivalent of university level.
    IV. **Cultural differences in maternity care**, the way midwifery is practised and women expectations should be taken into account when midwives are willing to practice abroad.
    V. Activities of midwives (article 42) needs to be reviewed, prescription rights should be more explicit, as well as the role of midwives as an autonomous practitioners.
    VI. Minimal list of competences necessary to perform the activities described in article 42 and linked to the training requirements is suggested by CAs; output based programme and not only input.

11. Some CAs wonder how they can be certain that the minimal training requirements are correctly implemented. There is no guarantee of this in the Directive. **Accreditation systems** may contribute to improve mutual trust.

12. Continuous Professional Development (CPD) is already mandatory in several Member States. A **definition of CPD at European level** would be needed. Some respondents are in favour of **mandatory minimum requirements for CPD at European level** (common framework for CPD at EU level). In future, CPD elements should be mutually recognised and transferred in each member state. The respect of CPD requirements should also be taken into account during the recognition process.

D. Administrative cooperation

13. **Direct contact and co-operation between CAs** increase mutual understanding and trust. The **Network of European Midwifery Regulators** is mentioned by several CAs as a useful initiative. This opportunity to meet and establish direct personal contact facilitates administrative cooperation.

14. The big majority of respondents are registered within the IMI system. Some use this more than the others but all underline the benefits of this system for administrative cooperation. Some Competent Authorities are in favour of making the **use of IMI mandatory** or **further developing it** (alert system to inform proactively other CAs in a secure manner). **Stricter deadlines** to answer the questions may also be useful. Efforts could be done to make the system more user-friendly. Some CAs suggest creating a **feedback/auditing system in IMI** (from users to the European Commission) in order to quickly identify administrative problems. Many CAs regret that free text can only be translated into 6 languages and not into Eastern languages.

15. Professional cards are generally considered to be an interesting idea but also a **project difficult to put in place in the 27 Member States**. Professional cards aren't widely used in EU Member States. Some CAs underline that the kind of tool (card...) is not the most important but the fact to have reliable electronic certificates for the identification of health professionals. Respondents' views about the authority/organisation that should deliver the card vary. Other issues such as: secure access, up-to-date information, possibility to really make registers & database interoperable, costs etc. remain to be clarified.

16. Possibilities for exchanging information about suspensions/restrictions differ from countries to other. The Healthcare Professionals Crossing Borders Initiative promoting **proactive information exchange** is mentioned by several respondents.

Many authorities think more could be done to increase the exchange of information on fitness to practice.

17. Other observations
    a. On the issue of language skills, there are big differences of interpretation of the directive. Competent authorities widely agree that **language checks being done after registration are insufficient** to ensure the safety of mothers and babies. Lots of examples have been collected of complaints about insufficient language skills of migrants. Some CAs consider that knowledge of technical and medical vocabulary is necessary and should be checked.
    b. Some Competent authorities **charge fees for the recognition process.**

17 September 2010

Contact

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Bureau de Bruxelles

SYNTHESIS OF THE NATIONAL EXPERIENCE REPORTS ON THE DIRECTIVE 2005/36/EC RELATIVE TO THE RECOGNITION OF QUALIFICATIONS FOR PHARMACISTS

17 SEPTEMBER 2010

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The European Commission has launched an assessment of the existing system of recognition of professional qualifications, in the perspective of the revision of directive 2005/36/EC.

In this context, DG MARKT would like competent authorities in the Member States to prepare national reports presenting their practical experience in applying this directive. Mr Patrick Fortuit has been charged to coordinate this process for pharmacists at European level (see letter attached).

Consistently with the approach proposed by the Commission, 3 meetings of the competent authorities for pharmacists were organised:

- On the 7th of June 2010, in Brussels: This meeting aimed at discussing the questionnaire proposed by the Commission, adapting it to pharmacists' issues, and validating it as a basis for national experience reports.
- On the 9th of July 2010, in Brussels: During this meeting, projects linked to the European directive (IMI, HPRO) were presented and a debate was organised on the several parts of the questionnaire in order to exchange on the situation in various countries (on recognition in case of migration on a permanent basis, on temporary mobility, on minimum training requirements and on cooperation between competent authorities).
- On 3rd September 2010 in Paris, a draft synthesis of the national reports was presented and debates organised according to the several parts of the questionnaire. Malta was in charge of commenting the answers to part A (with exception of the first question) of the questionnaire, Denmark in charge of part B, France in charge of part C and Belgium in charge of parts D and E.

The questionnaire validated on 7 June 2010 was sent out to competent authorities in the 27 member states, answers to the questionnaire are annexed to the present document.

This document intends to give an overview of the answers received.

This synthesis was elaborated thanks to the contribution of competent authorities from Malta, Denmark, France and Belgium.

PART A: RECOGNITION PROCEDURE IN CASE OF MIGRATION ON A PERMANENT BASIS

Question 2: To what extent have the system of automatic recognition and the general system been a success? How do you see the costs and benefits? Specify in particular whether automatic recognition based on diploma, Annex V and the current notification system represent an efficient way to facilitate automatic recognition. Please submit comments for: automatic recognition based on diploma; acquired rights and on the general system

Question 3: Is the general system (as described in article 10) applied in your country each time the conditions for automatic recognition are not met? Are there major difficulties in the recognition procedure under the general system? Please include any comments you might have concerning the implementation of compensatory measures.

Question 4 : What is your experience with the recognition procedure for EU citizens with professional qualifications obtained in a third country and already recognised in a first Member State (See Articles 2(2) and 3(3))?

Question 5: Do you accept applications from EU citizens for the recognition of foreign diplomas sent by email or requests made on line? Under which conditions can they send documents and declarations electronically? What are your experiences in this respect?

Part A of the questionnaire is relative to the recognition procedure in case of migration on a permanent basis. It has to be noted that the analyse will only be on question 2 to 5, because it was seen as not relevant to make such an analyse on question 1 on government structure of every competent authority as each answer can be looked at in the annexes.

Automatic registration based on diploma

The majority of those that replied declared that **this system is effective and fast and facilitates the recognition process since the qualifications are listed in the annex.** Another positive note is that this system reduces documentation.

On the negative side, this permits pharmacists to be registered even if they have not practiced for a number of years. From the patients' point of view, since language is not a barrier, this might create problems. Germany also mentioned the fact that specification regarding diploma have to be kept up to date (in particular the wording in German is not accurate anymore).

Recognition based on acquired rights

There are a couple of countries such as Malta who have not yet experienced this type. The majority said that this is a fast and effective way for recognition.

Automatic recognition based on acquired rights is an advantage since the person can benefit from automatic recognition only if has the certificate of working experience. But because Directive doesn't specify how many hours person has to work in order to get the certificate of working experience, person can get it also if he works part time. However the Netherlands explained they experiences socme problems with this possibility in particular when certificates are issued wrongly.

The UK raised the issue that there is no mention of the validity of the acquired rights document and feels that this should also have a validity of 3 months from issue.

There was also an issue raised by Hungary on the amount of hours of work that will be valid for acquired rights since there is no mention in the Directive.

Hungary has also raised an issue about the interpretation of 'effective and lawful practice'. The language issue is also of concern to most countries.

Recognition based on general system

The majority agree that this is the **most time consuming of all three systems.** However, it is very exact as the education programme is compared with the programme valid for the particular country in which the applicant is applying. This is more costly for the applicant and administratively more resource intensive but public safety can be taken into account to a certain extent as if the comparison reveals substantial differences can require a period of adaptation training with assessments. The benefits of this system are that it provides the Member State with an assurance of an applicant's current knowledge and competence.

Come country also presented the problem related to the timeframe of 3 months in which a Member State is obliged to reply to the applicants. Germany raised the difficulty to define proper compensation measures. The Netherlands pointed out the costs of organising tests.

The majority of replies indicated that yes, the general system is used when the conditions for automatic recognition are not met.

The UK indicated that the general system of recognition is only applied within the limits permitted by the Directive i.e. within the parameters of Article 10(b) and 10(g). Applicants not entitled to automatic recognition and not covered by the General Systems provisions of 10(b) and 10(g) are considered under the provisions of the EU Treaty and ECJ jurisprudence.

In the case of Belgium, the provisions of the general system have not been trasposed into Belgian law.

There were a couple of countries such as Cyprus, Lithuania and Slovenia who have no experience of applying these conditions.

With regards to difficulties encountered, the majority of those that replied indicated that this system creates many difficulties since an application has to be assessed and evaluated in a short period of time.

Many countries also pointed out that this system creates a financial burden, whilst the applicants also find it difficult to undergo compensatory measures due to language restrictions.

Difficulties were also encountered in providing adaptation period and conducting training.

Recognition procedure for EU citizens with professional qualifications obtained in a third country and already recognised in a first Member State (See Articles 2(2) and 3(3))

This instance seems to be not so common in the Member States. Those who have experienced such cases said that they apply the Hocsman case. Some countries declared that this system is used by applicants who try to find easier routes for registration and then come back to their Home MS to register on the basis of their first recognition in another MS.

Applications sent by email or requests made on line

The majority have declared that they do not accept applications by email or online since the presentation of the physical documents is needed. Most countries provide details as well as registration packs and information by email and online.

Those that declared that they accept applications online or via email, still need the applicants to present their certificates in physical format.

Denmark, Luxembourg and Hungary have replied that they recieve applications online even though their experience is limited and that from their experience it transpires that applicants like the physical contact when applying. Most respondents declared that they do recieve applications via post just as long as all documents are certified, translated and in order. In teh Netehrlands only additional information can be sent out by e-mail. Some countries replied that an on-line facility is likely to be introduced in the near future.

PART B: TEMPORARY MOBILITY (OF A SELF-EMPLOYED OR AN EMPLOYED WORKER)

In this part the following questions were asked:

Question 7: Are EU citizens interested in using the provisions for exercising their professional activities on a temporary and occasional basis in your Member State? How many citizens used this new system since the directive has been transposed in your country (can you provide any statistics per month, per year)[1]?

Question 8: How are the provisions of Directive 2005/36/EC concerning temporary mobility applied by the competent authorities in practice taking into account the relevant provisions of the Code of Conduct? For instance:

- How is the "legal establishment" criteria foreseen by Article 5(1) (a) interpreted in practice? What conditions does a migrant need to fulfil in his home Member State in order to be able to provide services?
- How are the "temporary and occasional basis" criteria foreseen by Article 5.2 interpreted in practice? Do Member States assess duration, frequency, regularity and continuity of an activity and if so according to which criteria?

Question 9: Why is a prior declaration system necessary? What do competent authorities do with the information received? Are other possibilities conceivable?

Question 10: Do you have concrete examples of abuse or misuse of this new possibility for pharmacists? Have you been confronted to problems with regards to patient safety on this issue?

Experience to date

In general most countries have little or no experience with pharmacists whom wish to exercise their professional activity on a temporary and occasional basis in another Member State. In the Netherlands, it is interesting to not that there is another possibility for pharmacists to work on a temporary basis; pharmacists can work on order of a Dutch pharmacist. This is to say that the Dutch pharmacist is responsible of the foreign pharmacist.

The United Kingdom[1] has had two inquiries to date – the applicants choose to apply for establishment instead when they realised they did not have the right to automatic recognition. Denmark, France and Spain have had a few inquiries and one declaration.

Italy has very few pharmacists that exercise their professional activity on a temporary and occasional basis, while in the Czech Republic they had 7 applications in 2009 and have registered an increasing interest from pharmacists who wish to exercise their professional activity on a temporary and occasional basis.

[1] *The Competent Authority for England, Scotland and Wales will be referred to as the UK in this document.*

Hungary has believes that the reason why the number of the declaration concerning temporary mobility is very low is due to the fact that the service providers do not always inform the authorities about their service or that they do not know about this obligation or find that the procedure is too complicated. Spain is of the opinion that applicants prefer to apply for permanent recognition, which means that they do not need to renew their application and which does not require prior declaration of the provision of services they intend to carry out.

Spain has pointed out that the relatively low number of declarations might be explained by the fact that the procedure relating to establishment is virtually the same as the procedure for temporary provision of service and furthermore pharmacists might choose establishment in order not to have to renew their declaration annually.

Practice in general

In general Member States require the service provider to submit information in accordance to article 7 of the directive 2005/36 EC and the code of conduct.

The Czech Republic operates with two types of declarations for temporary provision of service. The most common declaration is the announcement of the visiting person for the medical profession performance, which is time-limited for one year. Another possibility is the so called one-time performance announcement when it is only needed to submit to the Ministry of Health a letter declaring that the applicant has been invited by a health institution for a "one-time performance".

In Italy the information received is forwarded to the competent Order of Pharmacists that is responsible for the territory in which the migrant will be provisionally enrolled during his performance.

In Denmark, Ireland and Slovenia the service provider is entered into a register.

Furthermore, the Slovenian authorities collect information for statistical and analytical purposes, and the information is also used for annual reports to the European Commission.

Interpretation of legal establishment

Legal establishment is interpreted in Denmark as meaning that the applicant has an education automatically recognised under title III chapter III of the directive 2005/36 EC. In cases where the service provider does not have an education which benefits from automatic recognition, the professional qualifications must be verified. Finally the service provider has to document that he or she has not been prohibited from practicing as a pharmacist.

In Ireland the term "establishment" is defined as being the actual pursuit of an economic activity, as referred to in Article 43 of the Treaty, by the provider for an indefinite period and through a stable infrastructure from where the business of providing services is actually carried out.

Legal establishment is in Belgium interpreted as being the obligation to be registered with the Pharmacists Organisation in the Member State and to be authorised to exercise the profession without restrictions or being subject to sanctions.

In Cyprus the migrant must be a registered pharmacist of good professional standing in the country of origin in order to be eligible to either provide services or be established permanently in Cyprus.

France has the understanding that pharmacists are required to be registered by a competent authority in order to constitute "legal establishment".

In Luxembourg the criteria is analysed individually for every application. The migrant must hold an authorization to practice in his country

The UK states that 'Legal establishment' for the sectoral professions appears to be interpreted as the right to practise in the home Member State without the need for evidence that the individual does indeed practise – i.e. evidence of a subsisting contract for services or contract of employment. Legislation must provide for a clearer definition of what is meant by the practitioner being 'legally established'. According to the UK it should be more than being qualified to practise with no prohibition from practice (even temporarily). The UK also does not believe that the directive is sufficiently robust to protect members of the public and patients. The Directive only requires the applicant to demonstrate that they are 'legally established' in a Member State for the practice of their profession. Persons wishing to avoid disciplinary proceedings or who have been removed from practice in one Member State may move from one jurisdiction to another, continuing to rely on 'legal establishment' in a Member State which maybe unaware of any fitness to practise allegations or history of such proceedings in other Member States.

As a 'risk based' regulator, the UK sees this as an area where any person wishing to circumvent reasonable regulatory process may target.

Furthermore the Directive only requires the person to be legally established for the purpose of pursuing the 'activities concerned'. It provides no safeguards in cases of dually qualified persons in circumstances for example where a practitioner who is dually qualified as a doctor and pharmacist, and who has been prohibited from practising as a doctor in his home Member State nevertheless relies on establishment in a Member State as a pharmacist to continue to provide services as a pharmacist in other Member States. Furthermore, the UK remains concerned that they cannot require prospective temporary service providers to complete the same fitness to practise declarations prior to registration as we require of national or European registrants applying to either join the Register or to renew their registration annually. Finally the UK is of the opinion that it would be very helpful if in a review of the Directive the role of the Competent Authority charged with recognition could be clarified in relation to the process that can exist for the authorisation of temporary service provision in a host MS.

Spain interprets "legal establishment" as the applicants' submission of a supporting certificate issued by the relevant authority of the Member State of establishment.

Conclusion

Member States do not have a common interpretation of the notion "legal establishment" apart from the service provider not being prohibited from practicing as a pharmacist in the Member State of Establishment or other Member States.

Interpretation of "temporary and occasional basis" criteria in practice

In Denmark "temporary and occasional basis" is interpreted as a visit or a stay of a period of up to max. 12 months. The applicant is not required to inform the authorities about the duration of his or her stay, as the applicant is not required to give information about contracts.

The Czech Republic has two types of applications for the limited period of time. Most common is the announcement of the visiting person for the medical profession performance that is time-limited for

one year. Another possibility is a so called one-time performance announcement with a maximum time of two months.

"Temporary and occasional basis" has not been defined in Ireland. The Council of the Pharmaceutical Society of Ireland is required to assess, on a case by case basis, the temporary and occasional nature of the provision of the professional services of a registered pharmacist by a visiting pharmacist form another State, having regarded in particular to its duration, its frequency, its regularity and its continuity. Since the question has not yet arisen, no criteria have been laid down.

The applicant must inform the Slovenian authorities about the duration and how often the applicant intends to perform services in Slovenia. The authorities decide in each case on the basis of the information given by the applicant whether or not the service is "temporary and occasional".

The criteria are reviewed on a case-by-case basis in Luxembourg and France, by taking into account the individual characteristics of the declaration made by the service provider. France is of the opinion that the term 'temporary and occasional' is ambiguous and would appreciate further clarification about these notions. France considers that a length of time should not be specified, but it would be appreciated if some specific indications could be defined.

In Spain, service providers shall describe the services to be provided in their prior declaration, with particular reference to their continuity or temporality, as well as to their periodicity.

Conclusion interpretation - "temporary and occasional basis" criteria

The majority of the Member States requires that the service provider is authorised to exercise the profession without restrictions or being subject to sanctions. Besides there is no common interpretation of the notion of "legal establishment".

In general the Member States do not have a common view on the duration of the in order for it to be *"temporary and occasional".* The duration seems to be interpreted as being somewhere within one day and 12 months.

Most Member States asses the *temporary and occasional basis* on a case by case basis. They do so by applying the information given in the declaration by the service provider.

Why is a prior declaration system necessary?

Austria points to the fact that temporary mobility may lead to abuse through by-passing the recognition formalities.

In Cyprus, a prior declaration is necessary to determine the professional qualifications, nationality and indemnities of the applicant as well as to allocate responsibility in the case of false statements and professional misconduct.

Belgium finds that the preliminary statement allows the competent authority to verify with the Member State where the professional is based, whether the latter is legally authorised to exercise his profession.

Hungary is of the opinion that prior declaration/notification is essential because that is the only guarantee the service provider can be supervised by the national authorities in the Member States. The system could work more efficiently, if common sanctions in case of non compliance with the requirement of prior declaration were developed.

Denmark is of the opinion that the declaration system is needed in order to avoid that applicants bypass the procedure concerning establishment under Title III Chapter III of directive 2005/36 EC.

According to Spain a prior declaration is necessary since it replaces the application for recognition and specifies the temporality of services.

Italy, Ireland and the UK find that a prior declaration system is necessary in order to secure patient and public safety. With a prior system of declaration the competent authority has the opportunity intervene before service provider causes damage to patients or public. Furthermore, the UK is of the opinion that prior notification will enable the Member States to verify migrants' identity and qualifications. If the migrants are not entitled to automatic recognition there can be a prior check of their qualifications before the first provision of services is permitted in the interests of public and patient safety. Under UK legislation before anyone can call themselves a pharmacist or practice as a pharmacist they must be registered with the competent authority. A prior declaration is necessary in order to ensure that only eligible individuals are placed on the register before they can provide a service.

France is of the opinion that a prior declaration system is pertinent in order for the competent authority to organize test for declarations within in the general system. The temporary provision of services should not be used by professionals whose diplomas do not meet the criteria for automatic recognition to benefit from this principle to practice in another country.
Furthermore, France points out that it is necessary for the national authorities to receive information on pharmacists practicing on national territory – e.g. in relation to a health crisis or professional misconduct leading to a disciplinary actions.
Finally, France stresses that the temporary provision of services should not offer the opportunity for professionals prohibited from practicing in one Member State to practice in another Member State.

France proposes that the service provider in the future should be obligated to add information about on the first practice place in the host Member State in order to facilitate the internal administrative processing of prior declarations. In cases of professional misconduct the case should be registered with the competent disciplinary chamber.

Conclusion

The prior declaration system is necessary in order to ensure patient and public safety. Furthermore, the system enables the competent authority to check service providers without an education automatically recognised under the directive and to register service providers acting on national territory. Finally the declaration system is pertinent in order to avoid that migrants bypass the automatic and general recognition of establishment procedure as well as avoiding that pharmacists prohibited from practising in other Member States become a service provider in another Member State in order to circumvent a national prohibition to practice.

Examples of abuse or misuse of the right to provide service on a *"temporary and occasional basis"*

The Member States have no examples of misuse.

PART C: MINIMUM TRAINING REQUIREMENTS – DRAFT SYNTHESIS OF THE ANSWERS RECEIVED

The four following questions were asked to competent authorities:

Question 11: To what extent are the common minimum training requirements set out in Title III Chapter III of Directive 2005/36/EC and the compulsory training subjects as defined in Annex V in line with scientific progress and professional needs? Furthermore, are the knowledge and skills required by the directive still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

Question 12: To what extent are the common minimum requirements for training set out in Title III Chapter III of Directive 2005/36/EC in line with scientific progress and professional needs in the last ten years? Are the knowledge and skills outlined in Article 24.3 still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

Question 13: The Directive is based on mutual trust between Member States. To what extent is such trust actually achieved? Are training programmes accredited in your country? Does accreditation of a training program in another Member State enhance trust or is it not relevant?

Question 14: To what extent are the existing Directive provisions (see recital 39 and Article 22(b) on continuous professional development (continuous training) adequate? What is your definition of CPD/continuous training? Is continuous training mandatory in your country and what are the exact conditions?

In general Part C of the questionnaire relative to minimum training requirements seems to be one of the most difficult parts to complete. This could be explained by the fact that competent authorities as identified together with the European Commission on the evaluation of the directive for pharmacists have few responsibilities in this area. In fact it appears that competent authorities are in charge of the recognition of the diploma and not of the content of it. It appears also that at a European level faculties have the power to define programmes for pharmacists' education. The independence of faculties in order to define their own programmes could be seen as an explanation for fewer comments to this area of the questionnaire.

It has to be noted that the directive specifies (both in articles and annexes) the knowledge and skills required for pharmacists. These knowledge and skills were not modified since 1985 when the directive was first drafted. Competent authorities where asked to identify if the knowledge and skills listed in the directive were still adequate.

Even if as explained earlier most of the respondents felt it difficult to answer these questions. The **majority felt that the knowledge and skills listed were still adequate** (Austria, Czech Republic, Denmark, Italy, Lithuania, Portugal, Slovenia, Spain). In fact the topics listed are so general that even if there were evolutions these evolutions still fits in the text. However, some countries found that the knowledge and skills had to be adapted in order to take into account the evolutions of our society (Ireland, Cyprus, Belgium, Hungary, and France). In particular recent developments in the pharmacists' role known as "pharmaceutical care" are cited as an example in several responses to the questionnaire.

Suggestions were made in particular by Cyprus, Belgium, Germany and France). The purpose of the suggestions is to add some topics to the training subjects, knowledge and skills and not to delete anyone. The Netherlands in particular suggested detailing more the theoretical and practical courses. It was suggested to add the following topics to the pharmaceutical knowledge and skills:

- Clinical pharmacy: therapeutics, pharmacokinetics and communication
- Pharmaceutical care
- Behavioral sciences,
- Pharmaceutical care/Medicines management,
- Pharmacy management and leadership, Medical informatics,
- Complementary and alternative medicines,
- Business studies,
- Legislation, Professional conduct and ethics,
- Dietetics,
- Pathology,
- Biochemistry and molecular biology,
- Immunology,
- Biopharmaceutics,
- Biotechnology,
- Clinical chemistry,
- Clinical pharmacy,
- Pharma-coepidemiology and economics,
- Medical devices and quality assurance during the production and testing of drugs.

It was also suggested to add the following topics to the pharmaceutical activities:

- Pharmaceutical care
- Adequate capability to provide health and medicine information efficiently and effectively
- Adequate knowledge, skills and attitudes that will enable the provision of a safe, high quality service in all healthcare settings within a clinical governance framework that is focused on patient safety.

In the previous version of the directive (Directive 85/432/EEC), it was referred to further training that was being developed in Member States in certain aspects of pharmacy and to possible mutual recognition of qualifications in pharmacy specialities following co-ordination of training. Discussions to date have not led to agreement among Member States on co-ordination of training. Developments in aspects of pharmacy practice are, however, continuing. In the answers given it was felt important to recognise these developments. They are designed to improve further the high quality of pharmaceutical services provided to citizens and to encourage free movement by suggesting mutual recognition of specialities such as hospital pharmacy and clinical laboratory medicine. The possibility for pharmacists to specialise in some area (biology or hospital pharmacy for instance) represent a great opportunity to evolve on the employment market.

These answers reflect the current trends in the pharmaceutical sector. Indeed the traditional role of pharmacists to manufacture and supply medicines is changing. Recently, pharmacists have been faced with new health demands and in particular had to evolve into a more patient centred approach (known as pharmaceutical care). The shortage of some health professionals (in particular doctors) represent also an opportunity for pharmacists which were given some tasks that were used to be done by others. This is why pharmacists have a more direct role in counselling patients, supplying them information and even review, monitor and adapt the therapeutic when needed according to an appropriate plan.

N.B : During the FIP (international Pharmaceutical Federation) annual congress that took place from August 30th 2010 to September 2nd 2010, the FIP presented a study that was organised in 8 countries among which five are European ones (Australia, France, Germany, Italy, Portugal, Turkey, the UK and the U.S.) between April and June 2010.

The international survey on pharmacists' view on their changing roles" In this study, pharmacists had to pronounce themselves on their changing roles. 76% of pharmacists think that the most favourable part of their job is helping patients and patients contact because it increases patients' outcomes and increases the visibility of pharmacists. According to this survey 93% of pharmacists think more information and advice is expected that ever before. Moreover 78% of pharmacists think they are expected to provide additional services to patients. One of the questions asked in this survey is particularly relevant to the training of pharmacists. 2/3 of pharmacists estimate that their training does not prepare them for their current role. When asked what the critical success factors for the next generation of pharmacists are, pharmacists are most likely to volunteer:

- more and better services oriented towards patients;
- increasing and securing competences through initial and continuing education;
- increased knowledge (including specialisation);
- communication skills, patient interaction and counselling;
- disease management;
- Providing new services.

As far as the length of the training is concerned, all the respondents think the duration is fine. However, France and Ireland point out that the training period of 6 months **should be in block** in order to allow pharmacists to have the best possible training.

⇨ Mutual trust:

Most of the answers point out that mutual trust is achieved. The directive dates back to 1985 and the principle there exist for more than 20 years now. The case of Luxemburg is a bit special as no faculty exist and all the pharmacists have to be trained elsewhere. However some member states (mainly new ones) think that trust is not enough and ask for certificates (Slovenia and Lithuania).

In general the accreditation of programs is made by faculties. Ireland suggests in its answer that there should be an obligation for accreditation in each Member State. This obligation coupled with transparent accreditation criteria and transparent processes used to accredit the pharmacist qualification would greatly enhance the established relationships of trust across all Member States.

⇨ Continuing education:

At the meetings organised for this evaluation process there was general agreement that lifelong learning dimension is important due to the evolution of sciences and the changing role of pharmacists. However no clear definition does exist at European level, so it is not sure that every one understands the same with this concept (words lifelong learning, continuing education and CPD are all used).

CPD is becoming more and more mandatory (moral or legal obligation): According to the answers received Slovenia, Austria, Denmark, Hungary, Ireland, Italy, Cyprus, France and Belgium have obligations for continuous professional developments in their laws. In Spain and in Malta discussions ion this issue are going on.

Hungary, Ireland and France suggested going further by offering the possibility of validation of credits all over European. Some member state pointed out the interest of harmonisation in respect of national specificities. The creation of European cards for health professionals could be seen as a possibility to validate continuing education credits in all the European Union.

PART D: ADMINISTRATIVE COOPERATION

Question 15: To which extent does administrative cooperation simplify procedures for the migrant professionals?

Administrative cooperation improved since the IMI system has come into use (Belgium & Italy).
This tool has also cut down the response time.
Administrative cooperation simplifies the procedure for the migrant as relevant information is exchanged between authorities. (Denmark & Italy)
Trough a network of competent authorities, experience and information about legislations could be shared. (France)
The establishing of an informal network for pharmacists would be welcomed. This cooperation could simplify the situation of the applicants. (Hungary)
Administrative cooperation facilitates and fastens the recognition procedure. (Luxembourg & Slovenia
Administrative cooperation guarantees the safety of the recognition process. (Portugal)

Question 16: Is the competent authority in your country registered with IMI? Under which circumstances does your competent authority use IMI? If not registered, why not and what would be the conditions for changing the situation?

All countries answered that their competent authorities are registered with IMI.
IMI is used to reply to inquiries from other Member States and to contact and to request information from other Member States. (Portugal)
Some countries uses the IMI system to verify whether or not education is automatically recognised by the directive, when for instance the education is dated before the country's accession to the directive (Denmark). It is also used in case of doubt on the diploma or the degree or on some certifications presented by professionals (Italy & Luxembourg).
The IMI system is mostly used to exchange information concerning doctors and nurses, and not so much for pharmacists.

Various remarks made about the IMI system:

1. Getting translations of official documents is still a problem. (Austria)
2. Additional comments or information or an extra question is often needed. (Belgium)
3. The validation of the questions raised by a competent authority by the national coordinator delays the exchange. (France)
4. A current weakness in the IMI system is relating to the identification of just one competent authority in a Member State where the separate functions of confirmation of qualifications, and the information regarding current professional status, are carried out by separate authorities. (Ireland)
5. Direct contact between competent authorities for pharmacists has already been established and is already on-going, which reduces the need to use the IMI system (Ireland)
6. The use of IMI should be compulsory for all the Member States' competent authorities. The fact that this is not an obligatory system makes it less effective. (Hungary, Malta and the Netherlands)
7. There should be a time limit for countries to answer (The Netherlands)
8. IMI could be used more efficiently, if strict deadlines were built into the mechanism, as in some cases (and from some authorities) the answer arrives very slowly. (Hungary)
9. The questions specified are unsuitable for individual cases (Germany)

Question 17: How could a professional card facilitate recognition of professional qualifications of temporary services? Under which conditions could it be issued by a competent authority?

Most Member States are positive towards a professional card which can allow the qualified professionals to work in another EU country without having to provide many documents to the competent authority. Only the Netherlands does not see any added value of the card for the recognition of diplomas.

The card contains the essential elements to contact the competent authority in the migrants' country of origin, thus limiting the administrative procedures for the migrant. The card will bear a microchip that will work as a key to access the database of the competent authority of the country of origin and to know at any time the registration status of the health professional. (France)

A professional card enhances mutual trust. (Austria).

The card facilitates the recognition of professional qualifications and is also useful to give access to information about possible disciplinary sanctions pronounced by the competent authority of the country of origin. (Belgium)

Issuing a professional card demands a large number of migrant workers to be cost-effective. (Denmark)

However the card must be supported by an appropriate organisational procedural a technical infrastructure. (Ireland)

The information accessed by using the card, or printed on the card, has to be up-to-date and reliable. (Hungary, Portugal and Lithuania)

The card has to be issued by a national competent authority. (Luxembourg, Lithuania)

Professional associations issue the card if they are competent authority. (Slovenia)

For professions with a high level of mobility the professional card is important. (Austria).

The card could be used to submit certain documents, but it has to be standardised at European level (Germany)
The question of data protection has to be considered (Germany)

Question 18: How do you share information about suspensions / restrictions with competent authorities in other Member States? Could more be done in this respect?

At this moment information about suspensions and restrictions is exchanged through direct and personal contacts between competent authorities, mainly under request (Austria), or by using the IMI system (Denmark).

However the professional card could improve the communication of this information in real time (Belgium).

Concerns exist in some Member States about the authority to share this type of information arising out of the need to comply with data protection laws and these concerns exist notwithstanding the obligation towards that end that are contained in Article 56.2 of the Directive. It is noted that the Construction of Article 56.2 of the Directive, in providing that the data protection legislation be

respected, has left the door open to this particular (mis) interpretation. It is therefore suggested that Article 56.2 should be re-examinated so as to remove any such ambiguity.

The concerns for patient safety that would arise if this form of essential information were not to be shared, for whatever reason, are too great to be ignored and an appropriate amendment to the text would therefore seem to be necessary. (Ireland)

Two types of information sharing can be identified: reactive information sharing on case-by-case basis, and proactive information sharing. Some countries can only share information reactively because of the national data protection legislation. (Hungary)

It would be useful to identify the competent authority in each Member State in this field. (Luxembourg)

Some Member States requires a certificate of Current Professional Status and Fitness to Practise History (known as a "Letter of Good Standing) (UK and Spain).

Question 19: How and when are the necessary language skills of migrants checked after recognition of the professional qualifications? Are you aware of any complaints about insufficient language skills of migrants?

In most Member States the language skills of the migrant professional are not checked by public authorities after recognition. (Belgium, France, Denmark, Luxembourg

Only in case of doubt the health professional is asked to meet with representatives of the competent authority for an interview. This interview comprises an assessment test on the pharmacists' ability to communicate in the native language. (France, Portugal)

In other countries (Italy) language skills are checked after recognition.

In some countries the Code of Ethics or the Act provides that where an EU applicant for registration lacks the linguistic competence to be a registered pharmacist in the State, he or she must provide an undertaking to acquire it. (Ireland)

In Germany the applicant is asked to provide a certificate from a recognised language institute or in individual cases there is a personal interview with the migrant.

Most Member States consider that it is the employer's duty to ensure that the pharmacist has the required competence to communicate fluently with patients in the language of the country and that he has sufficient language skills. The Netherlands considers it incomprehensible that there is a possibility to be recognised and to register with insufficient knowledge of language.

Sometimes the applicant is asked to make a self-declaration concerning his language knowledge when he applies for registration.

All Member States believe that it is essential to ensure that health professionals who are in contact with the patients have sufficient language skills.

Complaints about insufficient language skills were made in Italy and Luxembourg. In Ireland concerns have been expressed about the limited ability in certain circumstances to communicate effectively with patients and their carers in the necessary counselling of patients on their usage of medicines.

CONCLUSION

This synthesis is the first step of the evaluation of the application of the directive 2005/36/EC on the mutual recognition of qualifications. The European Commission envisage to adopt a legislative proposal in order to review the above mentioned directive in 2012 based on the work done until 2011, in order to facilitate the mobility of workers and in particular pharmacists and to adapt education and skills to the needs of today's employment market and patients' needs.

Citizens and patients, when benefiting from cross-border services, should not have their health or safety put at risk and they should be assured of obtaining the highest level of quality and consumer protection. As a consequence, the provision of services should be subject to strict rules. Both host and home country rules and proper registration requirements should apply.

In the answers received it is clearly said that the system of automatic recognition for establishment can be considered as a success as it facilitates the procedure for both competent authorities and pharmacists. As far as temporary provision of services is concerned, competent authorities have only few experiences and it is difficult to draw conclusions at this stage.

The other main messages that have been identified are the following:

- Regarding minimum training requirements and compulsory training, skills and knowledge, the subjects defined in the directive are still in accordance because they are very general. However interesting suggestions are made by competent authorities in order to add new items and in particular to take into consideration the changing role of pharmacists;
- The duration of the training seems to be adequate, but the directive may suggest a number of hours as well and precise that the stage has to be in a block;
- Competent authorities are quite satisfied with the IMI system, even if some improvements need to be made (to become more user friendly and have all the competent authorities participating in the project);
- The question of languages skills is still a concern for competent authorities;
- Continuing professional development and continuing education are becoming more and more mandatory in the various member states, the directive should reflect this move and the possibility to validate continuing education credits in the entire European Union should be further explored;
- The use of professional cards (both for national and European purposes) issued by competent authorities represent an added value for the recognition of diplomas and facilitate the conditions of mobility for health professionals both for establishment and temporary provision of services.

LIST OF ANNEXES

1. Mission Letter from the European Commission
2. Questionnaire
3. List of Competent authorities contacted
4. Answers received

QUESTIONNAIRE

Evaluating the Professional Qualifications Directive
Experience reports from competent authorities

QUESTIONNAIRE FOR PHARMACISTS

A. RECOGNITION PROCEDURE IN CASE OF MIGRATION ON A PERMANENT BASIS

1. Please describe the government structure of the competent authority or authorities in charge of the recognition and of sanctions/restriction to practice.

2. To what extent have the system of automatic recognition and the general system been a success? How do you see the costs and benefits for patients and for your organisation?
Can you give concrete examples. Specify in particular whether automatic recognition based on diploma, Annex V and the current notification system represent an efficient way to facilitate automatic recognition.

Please submit comments for:

- automatic recognition based on diploma
- automatic recognition based on acquired rights

3. Is the general system (as described in article 10) applied in your country each time the conditions for automatic recognition are not met? Are there major difficulties in the recognition procedure under the general system? Please include any comments you may have on the implementation of compensation measures.

4. What is your experience with the recognition procedure for EU citizens with professional qualifications obtained in a third country and already recognised in a first Member State (see Articles 2(2) and 3(3))?

5. Do you accept applications from EU citizens for the recognition of foreign diplomas sent by email or requests made on line? Under which conditions can they send documents and declarations electronically? What are your experiences in this respect?

6. What is the yearly number of applications for recognition from 2000 to 2009? Please submit specific data for applications for automatic recognition based on diplomas, automatic recognition based on acquired rights (as from 2005), and recognition based on the general system[1].

[1] *Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.*

B. TEMPORARY MOBILITY (OF A SELF-EMPLOYED OR AN EMPLOYED WORKER)

7. Are EU citizens interested in using the provisions for exercising their professional activities on a temporary and occasional basis in your Member State? How many citizens used this new system since the directive has been transposed in your country (can you provide any statistics per month, per year) [2]?

8.How are the provisions of Directive 2005/36/EC concerning temporary mobility applied by the competent authorities in practice taking into account the relevant provisions of the Code of Conduct? For instance:

- How is the "legal establishment" criteria foreseen by Article 5(1) (a) interpreted in practice? What conditions does a migrant need to fulfil in his home Member State in order to be able to provide services?

- How are the "temporary and occasional basis" criteria foreseen by Article 5.2 interpreted in practice? Do Member States assess duration, frequency, regularity and continuity of an activity and if so according to which criteria?

9. Why is a prior declaration system necessary? What do competent authorities do with the information received? Are other possibilities conceivable?

10. Do you have concrete examples of abuse or misuse of this new possibility for pharmacists? Have you been confronted to problems with regards to patient safety on this issue?

C MINIMUM TRAINING REQUIREMENTS

11. To what extent are the common minimum training requirements set out in Title III Chapter III of Directive 2005/36/EC and the compulsory training subjects as defined in Annex V in line with scientific progress and professional needs? Furthermore, are the knowledge and skills required by the directive still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

12. To what extent are the common minimum requirements for training set out in Title III Chapter III of Directive 2005/36/EC in line with scientific progress and professional needs in the last ten years? Are the knowledge and skills outlined in Article 24.3 still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

13. The Directive is based on mutual trust between Member States. To what extent is such trust actually achieved? Are training programmes accredited in your country? Does accreditation of a training program in another Member State enhance trust or is it not relevant?

14. To what extent are the existing Directive provisions (see recital 39 and Article 22(b) on continuous professional development (continuous training) adequate? What is your 2 Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports. definition of CPD/continuous training? Is continuous training mandatory in your country and what are the exact conditions ?

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2 Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

D. ADMINISTRATIVE COOPERATION (THIS SECTION APPLIES TO ESTABLISHMENT AS TO PROVISION OF SERVICES)

15. To which extent does administrative cooperation, as outlined in Articles 8, 50, and 56 of the Directive, simplify procedures for the migrant professionals? Can you give your own experience?

16. Is the competent authority in your country registered with IMI? Under which circumstances does your competent authority use IMI? If not registered, why not and what would be the conditions for changing this situation?

17. How could a professional card (see Recital 32 of the Directive) facilitate recognition of professional qualifications and provision of temporary services? Under which conditions could it be issued by a competent authority?

18. How do you share information about suspensions/restrictions with competent authorities in other Member States? Could more be done in this respect?

E. OTHER OBSERVATIONS

19. How and when are the necessary language skills of migrants checked after recognition of the professional qualifications? Are you aware of any complaints (especially frompatients/clients/employers) about insufficient language skills of migrants?

20. Please fill free to add any comment you want on the directive 2005/36/EC

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LIST OF COMPETENT AUTHORITIES CONTACTED

Austria	Österreichische Apothekerkammer
Belgium	• SPF Service Public, Sécurité de la Chaîne alimentaire et Environnement, DG Soins de santé primaires et Gestion de crise • Ordre des pharmaciens, Conseil national
Bulgaria	• Ministry of Health • български фармацевтичен съюз (Bulgarian Pharmaceutical Union)
Cyprus	Pharmacists Registration Board
Czech Republic	• Ministerstvo zdravotnictví - oddělení lékařských povolání a uznávání odborných kvalifikac • Česká lékárnická komora (Czech Chamber of Pharmacists)
Germany	• National subdivisions exist. For the purpose of this evaluation it was decided to contact Bayern region who was in charge to coordinate with the other regional chambers • Bayern Landesapothekerkammer
Denmark	• Københavns Universitet - Det Farmaceutiske Fakultet • Laegemiddelstyrelsen
Estonia	Health Board (Terviseamet)
Spain	• Ministerio de Sanidad y Política Social (Subdirección General de Ordenación Profesional) • Consejo General de Colegios Oficiales de Farmaceuticos España
Finland	• National Supervisory Authority for Welfare and Health (Sosiaali- ja terveysalan lupa- ja valvontavirasto, Valvira)
France	• Conseil National de l'Ordre des Pharmaciens • Ministère de la santé et des sports (DGHOS)
Greece	Ministry of Health and Social Solidarity, Directorate for Health Professions
Hungary	• Egészségügyi Engedélyezési és Közigazgatási Hivatal (Office of Health Authorisation and Administrative Procedures)

Ireland	• The Pharmaceutical Society of Ireland
Italy	• Ministero del lavoro, della salute e delle politiche sociali • Federazione Ordini Farmacisti Italiani (FOFI) (Federation of the Order of Italian Pharmacists)
Lithuania	• Sveikatos apsaugos ministerija (Ministry of Health) • Farmacijos departamentas Department of Pharmacy (Ministry of health)
Luxemburg	• Ministère de la santé- service professions de santé, professions médicales et pharmaciens
Latvia	• Latvijas Farmaceitu biedrība (Pharmacists Society of Latvia)
Malta	Pharmacy Council, Health Division
The Netherlands	• Registratie en Informatie Beroepsbeoefenaren in de Zorg (RIBIZ) (Ministry department) • Registration and Information Health Care Professionals (Ministry departement), RIBIZ
Poland	• 20 regional chambers but the national level aggregates all regional chambers • Naczelna Izba Aptekarska (national pharmaceutical chamber)
Portugal	• Ministério do Trabalho e da Solidariedade Social • Ordem dos Farmaceuticos (College of pharmacists)
Romania	• Ministry of Public Health • The Romanian College of Pharmacists
Sweden	• Socialstyrelsen (The National Board of Health and Welfare)
Slovenia	• Ministrstvo za zdravje (Ministry of Health)
Slovakia	• Slovenská lekárnická komora (Slovak Chamber of Pharmacists)
United Kingdom	• Royal Pharmaceutical Society of Great Britain • The Pharmaceutical Society of Northern Ireland

ANSWERS RECEIVED

Cf. zip file for the answers received