Working document for pharmacists
European Commission Steering group professional cards
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- the Chamber of pharmacists from Belgium (Ordre des pharmaciens de Belgique);
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Chapter I - A possible card without chip

1. Background

Early 2007, a working group has been created in order to study a possible European card for health professionals. This group was composed by members of each five health professions (Doctors, Pharmacists, Midwives, Nurses and Dentists). They represented:

- European wide health professional associations,

- Competent authorities from the five professions listed in the directive originating from different Member states, Candidate countries or from European Economic Area (EEA)

An agreement was reached by the HPRO Card working group in July 2007. This format was officially presented at the European Parliament during a special event in Brussels on October 17th 2007 in presence, in particular, of Mrs Bernadette Vergnaud and Evelyne Gebhardt, two MEPs.

The main objectives of this project was be facilitate the free movement of health professionals in Europe while protecting patients from the small number of professionals that could be subject to severe disciplinary sanctions. In the future, the card could have other possible applications such as validation of continuing education, access to medical records …

The health professional European card will show two sides: one side is national, solely designed by competent authorities in line with local laws, the other harmonized side is European and clearly states the contact details of the competent authorities of the originator country.

The European side will be harmonized in all Member states. The name and address of the national competent authority will appear along with the European symbols. The card information will have to appear, at least, in the origin country language and in another language of the European Union. The following information will be mentioned on the card

- The profession,
- The logo of the competent authority,
- The name and contact details of the competent authority,
- A signature area,

The national side only will be different in each country and for each profession following the national regulations. At least, the name and ID of the health professional will appear on the card with a security hologram

This first step is merely visual but represents a great improvement in comparison to the current situation where it is sometimes difficult to identify which is the competent authority where the health professional is coming from. It would not require advanced technology, to allow direct access to the register of competent authority in the Member State of establishment.

Competent authorities would not have to issue a new document specifically for that purpose: professional cards existing for each profession at national level could include a standardized *'European'* part. This could appear on one of their sides, just like euro coins, which have a national side and a European one.

It has to be noted that some member states already use this card.

NB/ It has to be noted that if there are already any chips on the existing card (like on the picture) they could be used for national purposes only in the first step

2. Value added and legal effect of the card

At previous meetings of the steering group the Commission asked the following questions to participants:

- *What would be the value added of a European professional card?*
- *What problems could be solved with such a card?*
- *Should the European professional card have a common format for all professions?*
- *How could elements specific to particular professions be integrated?*

According to participants of the steering group, the aim of the card could be various:

- identification of a professional;
- enhancing transparency of qualification;
- facilitating recognition of professional qualifications;
- facilitating the communication between competent authorities to ensure that the professional is lawfully authorised to practice in the country of origin;
- speeding up the recognition process.

It has to be noted that these answers where given for all the profession covered by the directive and are not specific to pharmacists. In our view the added value has to be presented according to the categories of persons concerned: competent authorities/pharmacists/possible employer/patients. It could be summarised as follows:

Competent authorities (CA)	**Pharmacists/Pharmacists**	**Possible Employers**	**Patients**
Better communication between CAs	Facilitate the conditions of migration	Better knowledge of the "foreign" pharmacists/pharmacists (including possible information/detection of professional suspension or malpractice)	Protect patients from the small number of pharmacists that are at risk
Less paper	Use of a tool recognised at EU level	Employment facilitation	
Less bureaucratic		Help to fill out jobs more rapidly	
Follow up of migration			
Better control of professionals (including possible information/detection of professional suspension or malpractice)			
Elimination of language barrier (information for Cas should be in own national language)			

We consider that:

- The current system of automatic recognition is working well and that any amendment to this system should continue to be based on the diploma and annex V of the Directive.
- It is essential for patient safety concerns that the competent authorities are aware of the identity of all pharmacists practising on their jurisdiction.
- The recognition of Professional qualifications should be made easy as long as no harm for the safety of the patient can come from there and that there is a safeguard of the quality of healthcare services available to the general population;
- A European Professional Card that pursues these ends can be an added value in the identification of a given professional in a mobility regime as long as the costs associated to the

management of this card are proportionate and adequate to the financial ability of competent authorities.

3. Possible scenarios

The European Commission asked also the members of the steering group the following question "In which situation under the Directive 2005/36/EC the card could be used?" and presented several scenarios. These scenarios where adapted following the discussion at the steering group and mentioned in the green paper.

Temporary provision of services		**Establishment**	
Scenario 1	Scenario 2	Scenario 3	Scenario 4
The card would make any declaration which Member States can currently require under Article 7 of the Directive redundant.	The declaration regime is maintained but the card could be presented in place of any accompanying documents.	The card holder seeks automatic recognition of his qualifications: presentation of the card would accelerate the recognition procedure (receiving Member State should take a decision within two weeks instead of three months).	The card holder seeks recognition of his qualifications which are not subject to automatic recognition (the general system): presentation of the card would accelerate the recognition procedure (receiving Member State would have to take a decision within one month instead of four months)...

We believe that today it is quite complex for pharmacists that would like to move (but also for CA) to identify the right competent authority to send the application to. That is why we think the card could solve this problem. We appreciate that the European Commission has decided that the card will not represent a direct "entry gate" to the profession. In particular in the field of health, we think this could have serious implication on patient safety. That is why as far as temporary mobility is concerned we would favour scenario 2.

For temporary mobility it is essential that CA know the professionals that are practicing on their territory. In its green paper published on 21 June 2011, the European Commission is also suggesting that the card could replace all the accompanied documents but not the prior declaration. This scenario provides more guarantees in the case of pharmacists. The declaration can be used as an evidence to show that the pharmacist has been in that Member state providing a service.

We agree with the fact that the card could be used as a mean to facilitate the prior declaration system or to renew this declaration once a year. For the same reasons developed above, we appreciate the scenarios 3 and 4 identified by the European Commission for establishment.

It was suggested that if the card is going to be introduced it should be made available also for pharmacists that have obtained recognition through the general system.

4. Implementation challenges : Possible content of the card, Validity, Format of the card, link with IMI

a. Content of the card

We believe the content of the card is very much linked to the usage of it. We think the card should at list have the basic following written information on it:

- European Professional card;
- Profession covered/Qualification (i.e. pharmacist);
- Registration number;
- Name and surname of the holder;
- Name and contact details of the competent authority[1].

No other written information has to be on the card.

b. Implementation challenges

The implementation challenges for a card would be twofold:

- for the ones that do not have a card yet, they will have to create cards and set up a system for this;
- for the ones that already have cards, they would have to wait for the renewal of cards in order to incorporate the European Side of the card.

The card appears to be a technical solution to an administrative issue which is about the exchange of information concerning a pharmacist. We believe that there is an urgent need to first sort out and clarify the wider issues of the legal framework and the policy issues around for example the relative value of privacy versus data exchange.

c. Role of the home and host Member states

We agree with the proposals made by the European Commission in the framework of the green paper to mobilize greater the member state of establishment or member state of departure. The competent authority of the member state of departure is in our view responsible to verify that the pharmacist has all the required qualifications. This is very important in our view in order to increase mutual trust between competent authorities.

However, we believe that the competent authority of the host member state has the right to verify the information concerning the pharmacist that is applying for recognition of his/her diploma. However in order to accelerate this process, we fill that the use of IMI should be encouraged.

d. Link with IMI

We believe that the modernisation of the directive 2005/36/EC should include the mandatory registration within the IMI. This tool designed by the European Commission has proven great value for competent authorities in the past. However, it has to be noted that all competent authorities are not today registered within the IMI. Some countries have not even defined who the authorities are entitled to answer a question relative to a pharmacist.

As far as the link with IMI is concerned, we believe that the competent authorities that will issue the card will have to be registered with IMI[2].

We believe that the professional card should be linked to the IMI system in order that competent authorities of the member state of origin are responsible for making all checks in order to issue the card. A way should be find for the competent authority of the host member state to assess these documents.

[1] Competent authorities are defined in the directive 2005/36/Ec as "*any authority or body empowered by a Member State specifically to issue or receive training diplomas and other documents or information and to receive the applications, and take the decisions, referred to in this Directive"*

[2] At this stage it has to be noted that competent authorities are allowed to give the task of making the card to an external company

The European Commission has presented some projects on how the IMI could evolve. In those solutions, the use of existing cards was not taken into account as to our knowledge national cards already exists for pharmacists in the following countries: Austria, Belgium, France, Finland, Hungary, Italy (some regions), The Netherlands, Slovenia, and Sweden.

A solution could be to add to the physical plastic card some way of communication in a form of a web portal between the pharmacist and his competent authority unless the IMI could have a special access for the pharmacist wishing to move (this could be also thought for the potential employer).

Another solution could be that the internet web site of the competent authorities as listed in the IMI could provide an application allowing to every citizen by using the name of the pharmacist or his registration number have an access to the visual of the card and identify if the card is genuine or not. This is something that is already in place in Italy (Latina region) for doctors and dentists and could be adapted for pharmacists.

As a conclusion, the simple plastic card has been already created in some member state in Europe. This is a very simple and non costly initiative to put in place and might be used very rapidly everywhere in Europe. This step towards a European harmonised side could be identified as a first result of the works done by the steering group of the European Commission and could allow the European Commissioner Mr Michel Barnier to present some tangible realisations at the Internal Market Forum to be held on 3 and 4 October 2011 in Krakow under Polish presidency.

This simple card could evolve towards a card with a microchip as it will be explained in the second part of this document.

Chapter II - Second step: Card with a microchip

In this part of the document, we will see what could be the value added and implementation challenges of a smart card for pharmacists.

In the first part of the document, we presented the possibility to have a card without a chip and explained that this simple solution will not require having a direct access to the register of the competent authority in the member state of establishment. Such access would demand compatible national IT systems, which are complex and costly to develop. However, compatible systems at European level could be a worthwhile objective in the longer term. Every pharmacist can have a card, wherever he/she is working (community pharmacy, industry, hospital, clinical lab).

Any would -be employer or associate of the service provider, or any other interested person (e.g. a client or patient) should, if they so wish, be able to check that the professional's authorization to practice is not currently suspended in his Member State of establishment. The right to check the absence of sanctions should not, therefore, be restricted to *'competent authorities'* 1. Any interested person, at any time, should have the possibility to ask the relevant supervisory authority. Hence, the idea of a standardized European document that the service provider would carry and which would contribute to inform the service recipients, as provided for in Article 9 of the directive.

1. Value added and legal effects

The value added of the card would be the same as mentioned for a card without a chip, but other aspects will have to be added:

- Depending on the use of the card at national/European level: the recognition of diplomas will be faster so that the pharmacist will be able to work more rapidly;
- Depending on the use of the card at national/European level: possible validation of CPD credits and assessment of CPD situation;

- Depending on the use of the card at national/European level: authentication as pharmacist and access to e-health applications (e-prescription, patient record …).

2. Implementation challenges

The implementation of such cards within Europe implies that competent authorities at national/regional level have electronic databases. We are not sure that this is always the case. Moreover these data bases will need to have the minimum common items on them. As an idea these could be the items listed in Annex VII of the Directive 2005/36/EC. In depth studies should be made on the databases and on the way processes should be organised in order to allow access to information (by whom and under which conditions). It has to be noted that if competent authorities could always have more items in their databases only a minimum set of items would have to be identified for the purpose of the implementation of the card.

We believe that the more simple idea will where professionals who already use cards at national/regional level to update these cards and add a "European" function. For the ones that do not already have a card, the choice of using this card only for those that move or for everyone should be left to CA.

We believe:

- Transparency can only truly be achieved as long as authentication schemes to assess the veracity and validity of the professional card are put in place, avoiding its potential forgery;
- A European Professional Card should be more than just an identification card, which, on its own, would not facilitate de recognition of professional qualifications. It seems to be of more advantage a system that can store professional information and keep it up to date on the qualifications and the development of competences inherent to the pharmaceutical practice
- Interoperability criteria should be considered amongst member states as long as the timing and convergence methods for a common professional card in a way so that confidentiality of data and safety of support databases are assured.
- There is a technical challenge that could be potentially costly to be considered at the moment of conception of such a system and further study on the matter should be envisaged,
- The question of CPD has also to be taken into account,
- Automated translation tools have to be used in order to facilitate exchange of information between competent authorities
- There is a need for pharmacists to have a "physical card". In fact the pharmacists may have to present there card to other healthcare professionals in order to be identified as pharmacists.

3. Possible scenarios

We have the same comments on the scenarios identified by the European Commission in its green paper as for a card without a chip (see chapter 1).

4. Role of the home and host member states

We have the same comments on the scenarios identified by the European Commission in its green paper as for a card without a chip (see chapter 1).

5. Link with IMI

That is why we believe that existing information systems like the IMI have to be taken into account, incorporated and/or utilised.

We further believe that a European Professional Card should not exclude, by no means, the confirmation of professional data between competent authorities (that of the origin and that of the host member states) with the aim of confirming the updated references and if mention to applied sanctions on a national context of another member state. In this domain the IMI system could have a role.

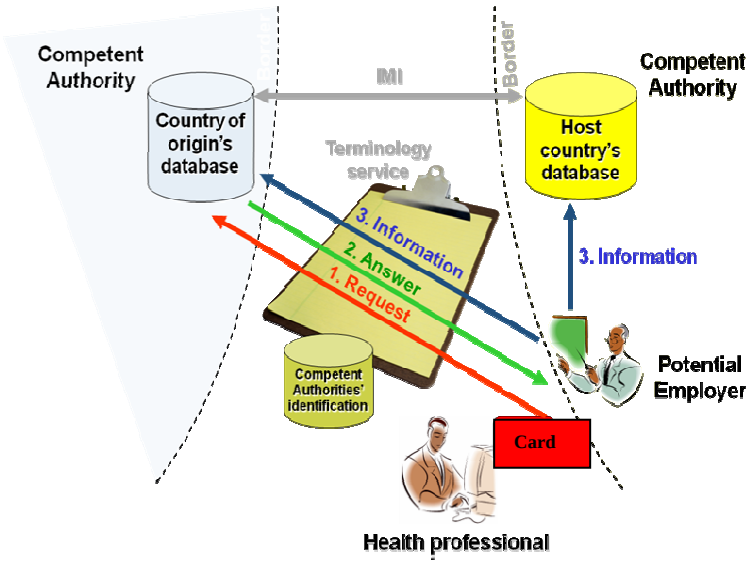
However the IMI system is not designed today to be linked to the future European cards that will be issued. It has to be noted that the European Commission envisaged the IMI tool to evolve and to allow a role in this issue. Some ideas were shared with participants of the steering group on 8 July 2011.

In particular, the European Commission suggested the card being possibly an e-card which is transmitted directly from competent authority to competent authority via the IMI system on behalf of an individual who wishes to practise in another jurisdiction. In that case, the use of the IMI would need to be mandatory and it would need to be used not only when exchanging information at the point of initial registration but also as an alert mechanism to alert competent authorities when any sanctions are imposed which restrict a healthcare professionals right to practise.

The e-card could be an electronic version of the certificate of current professional status which we already issue on behalf of registrants direct to the regulatory authority in the jurisdiction in which the individual wishes to practise. The certificate of current professional status confirms the registrant's name, date of birth, nationality, the title of their qualification and when and where this was obtained and the compliance or otherwise of the qualification with the Directive and provides information on any historic or current fitness to practise issues and whether or not the individual is currently authorised to practise without restrictions in his/her member state.

Links between the card, the IMI and online registers (when available) have also to be evaluated.

In turn, the card will hold some information (on a microchip) which could be used to contact the database of the competent authority of the health professional originating country and to check immediately whether or not the professional is entitled to practice (see proposed architecture below). The European card will still hold all national functions and will still follow the national legislation of the various member states.



We would like to identify two use cases:

- Use Case 1: A health professional wants to exercise in another EU country and has to prove his qualifications and abilities to practice
- Use Case 2: A sanction is decided in a country after the departure of the professional in another country

In the cases envisaged by the European Commission, it has to be noted that the information about a European pharmacist can only be given electronically if the university/body in charge of the diploma have the information electronically.

It has also to be noted that in some member states no disciplinary sanction exist.

Possible solutions:

Today the IMI is not generalised and all the competent authorities representing pharmacists are not registered in the system. This leads to a diversity of practices which may at the end complicate the life of pharmacists' whishing to move and making life more complicate for competent authorities to identify their counterparts and having answer to questions rapidly. That is why we believe this situation has to change and the registration in the IMI to become mandatory.

This perspective would lead to the updating of the list of relevant European authorities and facilitate the verification of health professionals' qualifications.

This should be accompanied by a standardisation of procedures employed by the competent authorities (e.g. with an agreement on the list of documents required for registration, on the questions/answers necessary for exchanges between authorities, on the profiles of people using IMI…).

This system would preserve its administrative purpose but it would not provide a solution for managing access rights to applications and on-line services of the health information system in Europe.

At this stage we think there might be several solutions as listed in the table below:

Solution 1: normalised processes and a centralised European database, with health professionals electronic certificates The management of professional qualifications at European level needs to standardise the process implemented by the competent authorities. So this organizational phase is common to all solutions In this scenario, the goal is to organise the processes around a centralised database that would consolidate all qualifications management information, places and exercise rights of European health professionals. This solution requires harmonising attributes recorded for health professionals in all jurisdictions of all the concerned Member States. The access to this database could be achieved via the IMI.
Solution 2a: normalised processes and decentralised databases, with health professionals' electronic certificates In this scenario, the goal is to organise the process around decentralised databases by country. Each database would include all qualifications management information, places and exercise rights of health professionals in the country. This solution requires harmonising attributes of information exchanged between countries. The access to these databases could be achieved via the IMI.
Solution 2b: normalised processes and decentralised databases, with cards This solution is the same as the solution 3a in which pharmacists' smart cards would be used to access the database in the cardholder's country of origin.
Solution 3: normalised processes with all the information on cards

This solution will require the deployment of pharmacists cards in each country. In this scenario, data are only present in the card (except the information on the rights of exercise and sanctions). They are accessed through the reading of smart cards and not by requesting a database.

We think solution 1 has to be rejected as this does not respect the principle of subsidiarity, where member states are able to organise their health systems. The competent authorities will also have huge difficulties to accept to delegate management of their database at European level. In addition, the creation of a big "European data base" is something complex to implement and that competent authorities at national/regional level will strongly oppose. They will favour the use of the existing databases (even if they may have to evolve a bit).

We favour solution 2 that could in our view increase mutual trust between competent authorities. However the system will be hardly accessible to professionals unless checkpoints are made accessible to them.

In the solution 3 the main problem is that the information is difficult to update (in particular information on sanctions and right to practise).

These solutions represent first ideas on how to use the IMI combined with a smart card and further analyse have to be made together with the persons in charge of the IMI system in order to see from a safety point of view and from an interoperability point of view what is thinkable.

e. Format of the card

It is necessary to define a mechanism in order to update or renew the cards that have been issued.

The final objective is to have cards bearing a microchip that could be updated constantly. The chip will bear an access key (no information is stored on the card). This key will allow the reading of the agreed items of the data base of the competent authority of the country of origin where the pharmacist is established. The data base of the competent authority of the country of origin is updated permanently. The continuous update of such a card represents the value added of the project. Authentication of pharmacists and e-signature will allow working on e-health possible applications such as European e-prescription as identified in the European Directive on patient's rights or on possible access to patient summary/patient records as currently evaluated by the European EPSOS project.

f. Major risk of not doing anything

We believe that if the Cas are not developing their procedures, there is a major risk that interoperability will not be achieved and the mobility of pharmacists will depend on the way competent authorities are dealing with those aspects. Jobs may not be filed on time and citizens will have to make huge efforts to have there diplomas recognised. That is why we think the development of such cards or certificates will have to be studied further. Impact assessments and technical pilot studies will have to be deployed at European level.

As a conclusion, it mentioned that the objective is not to create new cards, but to extend the use of cards that already exist at national/regional level. The main goal of this project should not be to facilitate as such the mobility of pharmacists but to facilitate conditions of mobility of professionals that are safe, in that way patient safety should always be on top of our priorities in that context.

It has to be kept in mind that the card alone will not work. It is crucial that a link to the register is created. That is why we think the cards should bear access key to the register of CA. Thus cards can be used not only for the purpose covered by Directive, but also for access to national eHealth applications, continual education … The directive could state minimal requirements for database or functionalities needed.

The final objective is to have a smart card (card with a microchip) where the information that it gives access to is constantly updated. More precisely our work should be on certificates that will be in the microchip and could in the future be incorporated by other tools that will appear thanks to the development of technology (for example smart phones …).