

DG Internal Market and Services Unit D-4 'Professional Qualifications European Commission Internal Market Directorate General, Unit D-4 Rue de Spa 2, Office 06/014 1049 Brussels, Belgium

12 March 2011

Dear Sir,

EIPG response to the Consultation on Professional Qualifications Directive

The European Industrial Pharmacists Group represents the national professional organisations of pharmacists employed in the Pharmaceutical and Allied Industries of the Member States of the EU. We are pleased to comment on the following questions in your consultation paper:

Question 11: What are your views about the objectives of a European professional card? Should such a card speed up the recognition process? Should it increase transparency for consumers and employers? Should it enhance confidence and forge closer cooperation between a home and a host Member State?

Question 12: Do you agree with the proposed features of the card?

Response: Whilst agreeing with the features of the proposed card, any professional card will only indicate that the person was registered on the date given on the card and would need to be checked against an online data base. Until there are accessible online registers throughout the EU, it seems premature to consider a card.

Question 21: Does the current minimum training harmonisation offer a real access to the profession, in particular for nurses, midwives and pharmacists?

Response: Yes, the current minimum requirements of the polyvalent undergraduate course in pharmacy including the pre-registration training do allow access into industrial pharmacy. However, the subject list needs updating.

Question 22: Do you see a need to modernise the minimum training requirements? Should these requirements also include a limited set of competences? If so what kind of competences should be considered?

Minimum training requirements

Response: Yes, there is a need to update the minimum training requirements with additional subjects listed in 1-4 below. The following are areas of great importance to the pharmaceutical industry and the pharmacists who work in it because our current pipelines are 30 to 40% biotechnology based. In the near future community and hospital

pharmacists will be involved with the storage and dispensing of these products. Therefore all pharmacists need knowledge of these new medicines and how to handle them. Many of them require distribution and supply via the Cold Chain.

- 1) The discovery and development of Biopharmaceuticals (includes proteins, peptides and monoclonal antibodies).
- 2) The discovery and development of Biologicals (which covers Vaccines).
- 3) The area of Genomics (which should cover personalized medicines and patient stratification)
- 4) Physical and Biophysical chemistry. Also Biological chemistry as traditional Analytical Chemistry does not cover all the fields of analysis necessary to support knowledge of the Quality Control in biologicals.

The Directive should include the possibility of the six-month pre-registration training being conducted as 3 months in a pharmacy open to the public or a hospital under the supervision of the hospital's pharmacy department and 3 months in industry under the supervision of an industrial pharmacist".

Should these requirements also include a limited set of competences?

Response: Not until key transferable competences are better defined and harmonized throughout Europe.

The current drive in academia is that every programme of studies should provide opportunities for students to demonstrate subject knowledge and understanding, intellectual development, key / transferable skills (competences), and other skills related to employability and personal development. At present, these are by no means harmonized.

Question 25: Do you see a need for modernising this regime on automatic recognition, notably the list of activities listed in Annex IV?

Response: Yes, pharmacovigilance should be added.

Question 27: Do you see a need for taking more account of continuing professional development at EU level? If yes, how could this need be reflected in the Directive?

Response: Continuing Professional Development (CPD) is an essential component of maintaining competence to practice. We support CPD as an obligation for professional practitioners, but recommend that regulators and professional bodies in individual states should have the freedom to define how this is implemented.

I should be pleased to respond to any matters of clarification.

Yours faithfully

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