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

14th September 2011

Dear Sir,

EIPG response to the Green Paper on Modernising the 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 on the Green Paper:

Question 2 a) and b) Professional Card
We agree that the proposed card would have the beneficial effects you describe. However, there needs to be a central "on-line" source of information for all professionals so that national Regulatory Authorities can check the registration status of an individual professional from any Member State. A centralised European source is not currently available for pharmacy nor do we believe for other professions.

Question 8 Regulated Education and Training
There are a number of generic skills which are relevant and need to be developed by all pharmacists such as "management" and "communications". We feel these are best covered as "competences" you describe under point 4.1 of the second phase of modernization.

Question 11 Partially Qualified professionals
The Directive should apply to fully qualified professionals.

Question 12 Alert mechanism for health professionals
To ensure public safety, we consider Option 2 is appropriate for all health professionals, including pharmacy.

Question 14 Three phase approach to modernization of minimum training requirements
As well as regulatory authorities and academics, it is considered important that professional bodies should be consulted on all 3 phases of modernisation.

There is a need to look at current practice in each of the professions in order to establish sets of competencies. Levels of competence also need to be defined, as described in the recently published PHARMINE report on pharmacy education.
As the concept of "outcomes" is new to many Member States, we question whether the time-table for completion of the second phase by 2014 is achievable. During the PHARMINE exercise, we found it better to spend time achieving a common understanding rather than trying to force early agreement amongst pharmacists having very different background educational concepts.
As mentioned previously, 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 many 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".

Question 15 Clarifying the status of professionals

No professional should be allowed to exercise their profession in any other Member State if they are not able to demonstrate they can exercise their profession in their home Member State. Therefore, the principle currently applicable to temporary mobility should be extended to professionals seeking permanent establishment.
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 Member States should have the freedom to define how this is implemented.
If an individual is moving from a country where CPD is not required to one where CPD is a statutory requirement, the registering body must be able to satisfy itself that the applicant is up to date in the area of pharmacy in which they propose to work.

Question 21 Expanding the list of pharmacist's activities

We agree that counselling, the provision of information, reviewing compliance, monitoring and adapting treatment when needed are all activities of the dispensing

pharmacist (and this is not only the community pharmacist.) As mentioned previously, pharmacovigilance should be added to the list of activities.

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

Yours faithfully

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