www.eshg.org
European Society of Human Genetics

Administrative Office:
ESHG c/o Vienna Medical Academy
Alser Strasse 4
1090 Vienna Austria

Phone: +43 1 405 13 83 20
Fax: +43 1 405 13 83 23
Email: office@eshg.org
membership@eshg.org

European Commission
Internal Market Directorate General, Unit D-4
Rue de Spa 2, Office 06/014
1049, Brussels, Belgium
Markt-pq-evaluation@ec.europa.eu

Ref: Official response of the European Society of Human Genetics (www.eshg.org) *to the „Consultation paper by DG Internal Market and Services on the Professional Qualifications Directive (Markt D.4D/2010/)*

Introduction

We are grateful to the Commission for providing this opportunity to contribute to the above-mentioned Consultation paper on the Professional Qualifications Directive. The European Society of Human Genetics (www.eshg.org; further ESHG) is a non-profit organization. Its aims are to promote research in basic and applied human and medical genetics, to ensure high standards in clinical practice and to facilitate contacts between all persons who share these aims, particularly those working in Europe. The Society will encourage and seek to integrate research and its translation into clinical benefits and professional and public education in all areas of human genetics.

ESHG has been involved, together with national human/medical/clinical genetics societies, in the recently adopted "COMMISSION REGULATION (EU) No 213/2011 of 3 March 2011 amending Annexes II and V to Directive 2005/36/EC of the European Parliament and of the Council on the recognition of professional qualifications" which recognized specialist training in medical/clinical genetics. Through this process, which started under the French/Czech EU Council Presidencies (www.eu2008.fr; www.eu2009.cz), and which both had as their priorities addressing rare diseases for which medical genetics is one of the key medical specialties, we have gathered significant experience in working with relevant national authorities and European professional organizations upon which we base our below specified position.

Following the sequencing of the human genome, clinical/medical genetics (both terms for the specialty are synonymous, and will hereafter be called **clinical genetics**) are becoming an integral part of modern medicine with an important role in most medical disciplines. Furthermore, recent technological advances related to laboratory genetics offer a quantitative leap in application of genetics not only in rare diseases, but also in the more common "multi-factorial diseases". In order to reach the potential of this important development, professionals involved in genetic laboratory analyses (specialists in **laboratory genetics**) need similar Europe-wide recognition given the increased need for sharing of expertise and cross-border mobility of such professionals. The wealth of DNA test-based information generated by laboratory specialists needs to be translated into medically relevant information to the patients by clinical geneticists and, when appropriate, also by genetic counselors and nurses, hereafter called **genetic counselors**. Thus, in summary patients with genetic disorders will greatly benefit from recognition of laboratory geneticists and genetic counselors.

The process of "recognition" of clinical genetics was complex and complicated, lasted over 2 years in total and involved a substantial effort in collecting EU-27 national postgraduate curricula and legal dossiers listing medical/clinical genetics, including endorsements from national professional bodies. This was done to reach the Qualified majority vote and comply with all requirements of the Recognition Committee, all in line with the current and rather complicated procedure for EU wide recognition. Details of this process are listed at the ESHG website under "Genetics as a Medical Specialty in Europe", see https://www.eshg.org/111.0.html.

In this respect ESHG very much welcomes that the Commission addresses three major challenges listed in the Professional Qualifications Directive, namely 1/ Simplification for individual citizens, 2/ Integrating professions into the Single Market, and 3/ Injecting confidence into the system.

ESHG's responses to the questions that are relevant for us and where we feel competent to respond:

Question 1*: Do you have any suggestions for further improving citizen´s access to the information on the recognition process for their professional qualification in another Member State?*

The ESHG supports the Commission suggestion to set up "Points of Single Contact" which could provide a "one stop" facility for professionals who generally find the administrative process cumbersome and often discouraging.

Question 2*: Do you have any suggestion for the simplification of the current recognition procedures? If so, please provide suggestions with supporting evidence.*

An updated Commission-sponsored online database of legal dossiers and postgraduate curricula for given professions would be very helpful and of aid to professional societies, such as ESHG, which had to invest a significant effort in compiling these (see https://www.eshg.org/111.0.html).

Question 3*: Should the Code of Conduct be enforceable? Is there a need to amend the contents of the Code of Conduct? Please specify and provide reasons for your suggestions.*

In general consensual codes of conducts approved by expert groups composed of Member State representatives should be transposed into national legislatures and/or become in the end legally binding in order to assure their general Europe-wide impact.

Question 5*: Do you support the idea of developing Europe-wide codes of conduct on aptitude tests or adaptation periods?*

The ESHG supports this idea very much for all of the three health-services oriented specialties: clinical geneticists, laboratory geneticists, and genetic counselors. We could together with national professional societies develop guidelines for aptitude tests and/or adaptation periods.

Question 7*: Do you consider it important to facilitate mobility for graduates who are not yet fully qualified professionals and who seek access to a remunerated traineeship or supervised practice in another Member State? Do you have suggestions? Please be specific.*

The ESHG has a long-term record of supporting young medical and non-medical graduates by fellowship to professional courses, such as those organized by Eurogene.org. An entire generation of fellows have benefited from these courses. Many genetics fellows also benefited from international mobility facilitated by the DG Research / REA – Marie Curie Actions. However, there is no consistent exchange of young graduates during their postgraduate training in clinical genetics or in laboratory genetics specialties. The ESHG could together with national professional societies develop a database of

opportunities for remunerated training in these specialties in other Member State. This would greatly benefit harmonization of best practice and provision of genetic services in Europe.

***Question 8**: How should the home Member State proceed in case the professional wishes to return after a supervised practice in another Member State? Please be specific in your reasons.*
In this instance the ESHG believes that a unified code of conduct (see above) developed with national professional societies would aid standardization of such procedures.

***Question 10**: How could the concept of "regulated education" be better used in the interest of consumers? If such education is not specifically geared to a given profession could a minimum list of relevant competences attested by home Member State be a way forward?*
The ESHG very much supports the introduction of a set of core competences for laboratory genetics and for genetic counselors in collaboration with national professional societies. We have a long-term positive track record in developing core competences for our profession (see https://www.eshg.org/139.0.html).

***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?*
The ESHG supports the idea of creation of a European professional card, in particular for the laboratory specialty and genetic counselors. This way their mobility could be facilitated within a very heterogeneous EU-wide environment of their "regulation".

***Question 12**: Do you agree with the features on the card?*
The ESHG supports all suggested features, and might add several more specific points for genetic counselors or nurses following consultation with national professional societies.

***Question 13**: What information would be essential on the card? How could a timely update be organized?*
In line with our answer to Question 12, ESHG suggests that an electronic update/verification system organized by Points of Single Contact at the Member State level could assure competent and verified updates. This authority should however closely work with respective national professional associations and/or medical chambers for medical/clinical geneticists, laboratory specialists and genetic nurses and counselors.

***Question 14**: Do you think that the title professional card is appropriate? Would the title professional passport with its connotation of mobility be more appropriate?*
ESHG has no preference in this regard.

***Question 15**: What are your views about introducing a concept of a European curriculum – a kind of 28th regime, applicable in addition to national requirements? What conditions could be foreseen for its development?*
ESHG, based on the very cumbersome and demanding procedure related to the recognition of clinical genetics in last two years, supports the Commission's proposal for a simplified system of "common platforms", which would enable development of European curricula. Our Society in collaboration with national professional societies could then develop a set of core competences for laboratory genetics and for genetic counselors. We envision setting up a European scheme whereby competences specified in common platforms could be certified by European board examinations, again in collaboration with respective professional societies and in compliance with respective national and European legal frameworks.

Therefore, ESHG supports the development of a European curriculum, constituting the "28th regime", which will be developed by us - in parallel and where possible in accordance with national training programs. All together we will comply with Commission standards and requirements.
The ESHG also very much supports the concept of reaching decision making "quorum" by Member states according to Article 9 of the Treaty, whereby only 9 Member States could vote for a measure as a minimum.

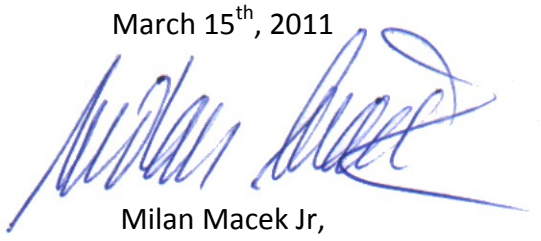
***Question 16**: To what extent is there a risk of fragmenting markets through excessive number of regulated professions? Please give illustrative examples for sectors which get more a more fragmented.*
Within health-care related genetic services the existence of the newly regognized specialty medical/clinical genetics, and the two related not yet-recognized specialties laboratory genetics and genetic counselors, should be adequate.

***Question 17**: Should lighter regimes for professionals be developed who accompany consumers to another Member State.*
Genetics is a one of the most important specialties for rare diseases, of which 80% have a strong genetic component in their pathogenesis. Clinical geneticists and genetic counselors are the first line of contact for affected families, and they often indicate that a set of laboratory examinations should be performed by qualified laboratory geneticists. Rare diseases have attained a special status due to their unique character by the Commission who issued in November 2008 – the "Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on Rare Diseases: Europe´s challenges", which was then followed in June 2009 by the „The EU Council Recommendation on an action in the field of rare diseases". The Council Recommendation has relevance for this question in that it stresses the role of health-care related genetic specialties. This document in its Recital 15 states, inter alia, that „expertise should travel rather than patients themselves". This statement provides the rationale for cross-border provision of genetic services by clinical geneticists, genetic counselors and laboratory specialists who could benefit in this regard from any such simplified procedure. Furthermore, if clinical geneticists are to travel in order to provide their expertise in another EU member state, these specialties would greatly benefit from this measure in particular in the view of the recently adopted "DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the application of patients' rights in cross-border healthcare", where rare diseases and the hence the three above mentioned genetic specialties received a prominent status. It could be envisioned that clinical geneticists under certain circumstances could, e.g. in the case of extremely rare disorders, accompany patients („consumers").

***Question 18**: How could the current declaration regime be simplified in order to reduce unnecessary burdens?*
Answer to this question is contained in the above-mentioned responses to Questions related to simplification of procedures, whereby electronic online modalities should receive priority.

On behalf of the ESHG executive board,

March 15th, 2011



Milan Macek Jr,
President of the European Society of Human Genetics