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European and External Affairs Committee

Date:	14 April 2005
Time:	9.00 to 12.30
Venue:	National Assembly for Wales, Cardiff Bay
Title:	Assessments of the impact of the EU Services Directive on Wales and the UK

AURE
Alliance of UK Health Regulators on Europe

THE EUROPEAN COMMISSION'S PROPOSAL FOR A DIRECTIVE ON SERVICES IN THE INTERNAL MARKET

A response by the Alliance of UK Health Regulators on Europe (AURE)

This paper has been produced by the Alliance of UK Health Regulators on Europe (AURE) in response to the Committee's Inquiry into the European Commission's proposal for a Directive on Services.

As regulators, AURE members have statutory responsibility for the protection of patients and service users. Our functions embrace the education and registration of health and social care professionals, the maintenance of professional standards and action against individuals who fall short of those standards.

AURE supports the aim of the proposal for a Directive on Services as a positive step towards facilitating service provision across the EU. Nevertheless, we firmly believe that in pursuing this goal, it is necessary to find the optimum balance between removing unnecessary barriers to cross-border service provision and at the same time ensuring the protection of the public interest (including public health).

Whilst we are pleased to note the inclusion of some checks and balances in the Commission's proposal, there remain certain areas of the text that need to be strengthened in order to enable competent authorities to carry out their regulatory functions and ensure patient safety across Europe.

The Annex to this paper outlines in further detail AURE's concerns as listed in the table below:

Measures of concern to AURE

- Single points of contact (Article 6)
- Authorisation schemes (Article 10)
- Cost of the authorisation procedure (Article 13 (2))
- Deemed authorisation (Article 13(4))
- Derogations from the country of origin principle (Articles 17 and 19)
- Exchange of information (Articles 33 and 35)

Single Points of Contact (Articles 6 and 7)

Article 6 states that a service provider must be able to complete *'all procedures and formalities needed for access to his service activities'* and *'any applications for authorisation needed to exercise his service activities'* at a single point of contact. This seems to imply that the contact point would orchestrate all the procedures, formalities and applications that a service provider might need to complete, liaising as necessary with regulators/competent authorities and others. AURE is concerned that, operating as an intermediary in this way, the contact point would in fact become an additional tier of bureaucracy between the service provider and the regulator potentially creating delay and/or misunderstanding.

We also note that the proposed role of the contact point goes much further than that envisaged in Article 57 (regulating contact points) of the most recent draft[1] of the proposed Directive on the recognition of professional qualifications. It is clearly essential that there should be a consistent approach across both Directives. The approach described in the Directive on the recognition of professional qualifications offers a more practical, and less bureaucratic, way forward.

In this context, AURE welcomes the recent Dutch Presidency working document (16th November) currently under discussion at Council Working Group level. This document adds a second paragraph in Article 6, which states that *"The creation of single points of contact does not interfere with the allocation of functions or competences among competent authorities"*. However, AURE would like to see this provision strengthened even further to state clearly that the provisions on single points of contact in the proposed

[1] Council Common Position of 21 December 2004, 2002/0061 (COD) Council Doc. 13781/2/04

Directive on Services shall not interfere with the allocation of functions or competences among competent authorities, or their pursuit of those functions.

- AURE would like to see explicit reference in the text to national competent authorities/regulators and the possibility for these bodies to play the role of the single point of contact where appropriate. AURE also asks that the relationship with the provisions on contact points in the proposed Directive on the Recognition of Professional Qualifications be more clearly defined.

Authorisation Schemes – Articles 9 and 10

Generally speaking, AURE supports the criteria laid down in Articles 9 and 10 for applying and operating authorisation schemes. We would take the view that the authorisation schemes operated by AURE members satisfy these criteria. Nevertheless, to ensure the protection of recipients of services in the health and social care sectors (who are often vulnerable patients), we wish to see it put beyond doubt in the text of the proposed Directive that authorisation schemes are acceptable for professions with implications for public health and safety.

The Directive must also make clear that nothing in the provisions of Articles 9 and 10 – or, indeed, Articles 14 and 15 on Black and Grey lists) - shall prejudice the ability of competent authorities to require service providers who have been authorised to pursue a service activity from demonstrating, from time to time, that they remain fit and competent to continue to pursue that activity. This is particularly important in the field of healthcare where competent authorities are now developing systems intended to ensure that healthcare professionals remain competent to practise throughout their working lives. Not only is this essential for the proper protection of patients, but it is also consistent with the provisions of the proposed Directive on the Recognition of Professional Qualifications which highlights the importance of life-long learning.

- AURE calls for Article 10 explicitly to permit the application of authorisation schemes for professions with implications for public health and safety and for the Directive to make clear that it is without prejudice to the ability of competent authorities in the health field to require service providers to demonstrate, at set intervals, their continuing competence to practise.

Authorisation procedures (Article 13)

AURE endorses the requirements laid down in Article 13 that authorisation procedures should be clear, accessible, objective and impartial. However, we have two areas of concern:

Cost of the authorisation procedure (Article 13(2))

Article 13(2) states that any charges which may be incurred from an application *'shall be proportionate to the cost of the authorisation procedures in question'*.

The UK competent authorities represented in AURE are responsible for a wide range of regulatory functions which are undertaken in the public interest. These include not only the granting of registration/authorisation to practise to healthcare professionals, but also responsibility for education, maintenance of professional standards and the operation of fitness to practise/disciplinary procedures for individuals who fall below those standards.

AURE's members are independent of the UK Government. They receive no funding other than through the fees paid by their registrants. These fees cover not merely the cost of registering/authorising an individual to practise, but they also take account of the wider regulatory functions that AURE's members are required to undertake in the public interest. AURE's members fully accept that they must ensure that the registration and annual retention fees they set are reasonable and proportionate to the costs of the responsibilities they are required to fulfil in protecting the public interest. However, this cannot be limited simply to the unit cost of the authorisation process itself and must reflect the full range of regulatory responsibilities to be carried out.

Since the definitions in Article 4 explicitly state that authorisation schemes cover both access to a service activity and the exercise thereof, it is essential that Article 13 (4) make clear that charges levied on applications may be proportionate to the costs of ongoing regulation by the competent authorities, not just to the unit cost of authorisation of access.

- AURE would like to see Article 13(2) amended to make clear that health and social care regulators who are independent of government can continue to charge fees that fairly and accurately take into account the costs entailed by the full range of their regulatory functions.

Deemed authorisation (Article 13(4))

Article 13(4) introduces the concept of 'deemed' registration/authorisation in cases where a regulator fails to respond to an application within a specified timescale. The processing of applications from EEA nationals is usually straightforward and completed within a brief timeframe. However, allowing health and social care professionals to practise in the absence of a response from the relevant regulator would encourage abuse of the system, undermine confidence in the registers, put patients at risk, and lead to confusion for both patients and employers.

We note that this Article permits different arrangements where these are objectively justified 'by overriding reasons relating to the public interest'. It is essential that the Directive makes clear that the definition 'public interest' covers cases concerned with public health and safety..

In this context, AURE welcomes as a positive step the introduction of a new recital 28 (a) in the recent Dutch Presidency working document in the Council, which makes direct reference to the possibility of exempting health services from rules on deemed authorisation by reason of public interest. However, to ensure fully that patient safety is

not compromised, it is necessary that this clarification be also included in the text of Article 13(4).

Moreover, we also take the view that the concept of an 'implied decision' should not be embedded in the definition of an authorisation scheme given in Article 4(6). If necessary, it should be contained in a separate definition which specifically excludes its application to professions with public health or safety implications.

Article 51 of the proposed Directive on the recognition of professional qualifications provides for an appeal under national law in cases where regulators do not respond to applications for authorisation within a specified time limit. We consider that, where public health and safety are at stake, this will provide a mechanism for holding regulators to account without undermining the regulatory regime which exists for the protection of the public. In any event, it seems appropriate that there should be consistency of approach across the two Directives.

- AURE calls for Article 13 (4) to make clear that health and social care services are exempt from rules on deemed authorisation for reasons of overriding public interest. In the same context, we also request that the concept of an 'implied decision' should not be embedded in the definition of an authorisation scheme given in Article 4(6).

Free movement of services: country of origin principle and derogations (Articles 16-19)

In discussions on the proposed Directive on the recognition of professional qualifications, it has been widely acknowledged that if health and social care professionals were able to practise temporarily in other Member States without being subject to regulation in the host State, patients would be put at risk. This view is reflected in the Council Common Position[2] reached on that proposed Directive where Articles 6 and 7 now provide for the temporary registration of individuals in professions which have implications for public health and safety.

AURE therefore welcomes the recent working documents of the Dutch and Luxembourg Presidencies in the Council of Ministers which seek to clarify further and confirm that the country of origin principle will not apply to professions with implications for public health and safety and will not affect the rules on the free provision on services as laid down in the proposed Directive on the Recognition of Professional Qualifications.

- AURE is calling for the European Parliament to strengthen the Commission proposal by further clarifying the exemption of healthcare professions and Title II of the proposed Directive on the Recognition of Professional Qualifications from the country of origin principle, as reflected in the recent working documents of the Dutch and Luxembourg Presidencies.

[2] Ibid

Exchange of information (Articles 33 and 35(3))

AURE is encouraged to see, in Article 33, that provision has been made for the exchange of information between competent authorities in different Member States about disciplinary measures against a professional. However, for professions with implications for public health and safety, it is not sufficient for this information to be provided on a reactive basis, *'at the request of a competent authority in another Member State'*. Rather, competent authorities must be proactive in disseminating information to all Member States where they have taken action against an individual who is unfit or unsafe to practise. This is vital if vulnerable patients are to be protected. Furthermore, a decision to communicate such information should not be based on a judgement about whether the individual *'is likely to provide services in other Member States'* (as suggested in Article 35*)* since the competent authority will not be in a position make such a judgement and also because the individual may hold registration in more than one Member State.

It should also be emphasised that the goal of effective information exchange is likely to be impeded in cases where professions are not regulated in all Member States.

- AURE would like to see the provisions on information exchange strengthened to provide for compulsory proactive information exchange among Member State competent authorities where an individual's fitness to pursue his or her profession is in question.

The Alliance of UK Health Regulators on Europe: who are we?

The Alliance of UK Health Regulators was established to safeguard the health and well-being of patients and service users to ensure that members of the public have access to and are treated by adequately qualified and competent professionals. As Regulators we are required to register for practice only those with the appropriate training and qualifications and who are able to communicate effectively with patients and service users. The Alliance lobbies on a range of European issues to protect patient safety.

If you have any questions or comments on the Alliance's position, please contact. Matthew Ball, Head of Public Affairs, General Medical Council, Convenor of AURE (Tel. 020 7189 5436, email: mball@gmc-uk.org).

Members of AURE:

General Medical Council	http://www.gmc-uk.org
General Dental Council	http://www.gdc-uk.org/
General Optical Council	http://www.optical.org/
General Osteopathic Council	http://www.osteopathy.org.uk/
General Chiropractic Council	http://www.gcc-uk.org/

Health Professions Council*	http://www.hpcuk.org/
Nursing and Midwifery Council	http://www.nmc-uk.org/
Royal Pharmaceutical Society of Great Britain	http://www.rpsgb.org.uk/
General Social Care Council	http://www.gscc.org.uk/
Pharmaceutical Society of Northern Ireland	http://www.dotpharmacy.com/psni/

AURE	http://www.aure.org.uk

*The Health Professions Council regulates the following 12 health professions: arts therapists, chiropodists/podiatrists, clinical scientists, dieticians, medical laboratory scientific officers (MLSOs), occupational therapists, orthoptists, prosthetists & orthotists, paramedics, physiotherapists, radiographers and speech & language therapists.