European & External Affairs Committee

EUR2 02-05(p4)

Date: 24 February 2005
Time: 09:00 - 12.30
Venue: National Assembly for Wales, Cardiff Bay
Title: BMA position paper on the draft EC Directive on Services

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Introduction

New proposals from the European Commission aim to boost the economy by creating a genuine internal market for the services sector. A draft directive introduced in 2004 will require Member States to justify existing and future national regulations to show that they are necessary and do not obstruct cross-border trade. Some requirements by national authorities will be banned straight away, others will be subject to 'peer review' with other Member States.

While businesses will welcome the removal of any unnecessary red-tape, the health sector has concerns that many individual national requirements that exist in the interest of patient safety may fall foul of Internal Market principles. The BMA has led the way in calling for health to be removed from the scope of the directive.

The British Medical Association believes that the draft directive fails to take fully into account the specific charachteristics of national health systems. As it stands, the proposals could threaten patient safety and undermine the ability of national authorities to govern their own healthcare systems.

Healthcare in the European Union operates under fundamental, social and public health considerations, is mainly financed by public funding and has a 'three-party model' (patient, provider and purchaser).

While it may be true that this draft directive would not force Member States to open services of general interest to competition, national health care systems would be exposed to the risk of being very deregulated because of the nature of the directive.

Health and healthcare services could be withdrawn from the scope of the directive by listing it as an excluded activity under Article 2. Although it is difficult to separate health and healthcare, in certain instances, from free movement of services, this could be achieved by excluding these services insofar as they are delivered on the basis of national solidarity that is partly or completely from social security contributions and other state funding.

This would allow for these services to be outwith the horizontal measures of the draft while at the same time subject to Treaty provisions on the free movement of services.

1. Responsibilities for the delivery of healthcare services of the Member States

Article 152 EC states that Community initiatives have to fully respect the responsibilities of Member States for the organisation and delivery of health services and medical care. The White Paper on Services of General Interest also stresses the importance of subsidiarity.

The draft directive does not go so far as opening healthcare to competition, nevertheless it will affect national planning policies and permit schemes by forcing national authorities to subject their requirements to scrutiny and in some cases abolish them.

It is important to note that national healthcare organisations need to set planning and permit mechanisms to guarantee access to and affordability and quality of healthcare.

Prohibited requirements and requirements subject to evaluation (article 14-15) (see point 2) as well as the Country of Origin Principle (Article 16) (see point 3) does not respect the power of national authorities to organise and deliver health services and medical care.

Article 9 will force Member States to submit existing authorisation schemes to peer review. National authorities are expected to screen their conditions for establishment on the basis of three criteria – non-discrimination, necessity and proportionality. This could expose national health care systems to the risk of deregulation. At present, national systems are governed by a set of rules restricting the access to and the exercise of health care services including; price and tariff setting , rules for continued training, registration procedures for providers, referral schemes and the use of clinical guidelines etc.

2. Prohibitions that reduce national control over health systems

Article 14 lists eight requirements to be abolished and article 15 lists requirements that should be assessed in a mutual evaluation report according to the three tests; non-discrimination, necessity and proportionality. Article 15 will weaken the ability of national authorities to organise their healthcare.

Article 14 directly challenges the responsibilities of national authorities to control their own healthcare delivery systems. Economic tests (prohibited by 14(5)) is needed for planning the amount of hospitals and healthcare equipment to ensure the access, affordability and quality of healthcare services.

Article 15 (2)(f) on requirements fixing a minimum number of employees could prevent Member States from maintaining minimum standards for personnel in hospitals and rest homes.

Member States lose the ability to introduce new requirements listed in Art 15, para 2 unless they pass the

test of non-discrimination, necessity and proportionality.

The Commission seems to assume the role of national authorities whose job it is to safeguard the access to, the affordability and quality of healthcare provided in their territory, according to Art 152 EC.

An independent study by the Catholic University Leuwen, commissioned by Ann Van Lancker MEP, Rapportuer on the Employment and Social Affairs Committee (October 2004) says, "it does not appear from the current wording of the Draft Services Directive that the power of national authorities to organise and deliver health services and medical care will be respected".

3. Cross-border freedoms that reduce ability of national systems to supervise

The Country of Origin Principle set out in Article 16 means that the host Member State will lose the power to impose registration on service providers. This could provide an incentive for providers to be established in a State that might keep lower standards.

A high degree of mutual trust would be required to enable sufficient supervision over the practice of a visiting doctor because of Article 16; especially so given that there are only minimal levels of harmonisation of health professions (in duration and content of training). Medical skills and competencies required to exercise each specialty vary greatly from country to country.

The Leuvan University Study says, "the lack of sufficiently harmonised mechanisms could entail the risk that national inspection services of the host Member State are completely sidelined by the Country of Origin principle". The Report adds, "further harmonisation at the EU level is needed in the field of quality norms, the protection of public order and minimum vocational training and qualification requirements for service professions".

The derogations from the Country of Origin principle do not go far enough. Derogations must be explicit enough to be beyond doubt. The derogation contained in Art 17 (8) for certain provisions of the Qualifications Directive is insufficient as it, again, assumes a level of harmonisation of health professionals that doesn’t exist.

Article 19 (1)(b) gives a derogation for health professionals but this is only on a case-by-case basis and in exceptional circumstances. This creates legal uncertainty. Furthermore it goes against the principles of Article 46 and 55 EC, being the free movement of services cannot prevent Member States from taking measures which provide for special treatment for foreign nationals on the grounds of public policy, public security and public health.

Healthcare should be removed from the scope of the directive

The BMA cannot support the draft directive as it stands and requests that health and healthcare services are withdrawn from its scope.

The BMA values the freedom of migration and cross border provision in the European Union. The BMA also welcomes moves to improve the legal basis for patient mobility, although Regulation 1408/71 is a better platform than the draft Services directive to facilitate this.

However, the draft Services directive fails to recognise that health and healthcare services should be governed by regulations for the purposes of health and safety and in accordance with the principle of subsidiarity.

We sympathise with the original aims of the Commission "to improve competitiveness and growth in order to meet the Lisbon goals" but remain to be convinced that these goals should apply to health services based on solidarity, equity and universality.