

European & External Affairs Committee

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Title: EU Directive on Services in the Internal Market

EU Directive on Services in the Internal Market

Community Pharmacy Wales submission to the National Assembly for Wales European and External Affairs Committee 24th February 2005

Introduction:

- Community Pharmacy Wales (CPW) is the representative body in Wales for the 700 plus community pharmacies that are contracted with NHS Wales. Membership covers a wide range throughout Wales from small independent chemists to the largest company chemists in the UK.
- CPW understands that the EU Directive provides a horizontal approach with a general legal framework applicable, subject to certain exceptions, to all economic activities involving services, including healthcare services. CPW is firmly of the opinion that this is not appropriate for the regulation of health services.
- The EU Directive establishes a series of measures aimed at ensuring freedom of establishment of service providers in other member states which, as it stands, will effect the provision of health services. These would remove Control of Entry regulations which relate to pharmacy availability in Welsh communities and on which the National Assembly has expressed strong opinions.
- The EU Directive establishes the "country of origin" principle whereby a service provider who wants to supply services to customers in another Member State would in general be subject only to the rules and regulations of the Member State where he or she is established. Thus a service provider would NOT be governed by the rules of the country where the service is provided. Thus service providers based outside the UK and operating in Wales would not have to comply with rules agreed for Wales, including legislation passed by the National Assembly for Wales.
- CPW is convinced that in order to guarantee a high level of public health protection, health services should be excluded from the scope of the proposal or dealt with under a different specific framework. This would ensure the special considerations and objectives, which define how health services must be provided at national level, are fully taken into account to ensure sustainable, high quality and universally accessible health services in Wales in particular and Europe in general.

Background

- **Horizontal approach**

In drafting this proposal the European Commission has opted for a horizontal approach. The proposed Directive will establish a general legal framework applicable, subject to certain exceptions, to all economic activities involving services. This blanket definition appears to include healthcare services. This horizontal approach is not, in CPW's opinion, adequate or appropriate for the regulation of health services. It does not seem appropriate to address health services, including pharmacy services, in a general manner, together with other services which are provided in very different ways and, which are subject to different legislative rules and market forces.

- **Freedom of Establishment.**

The proposal establishes a series of measures aimed at ensuring the freedom of establishment of service providers in other Member States which will affect the provision of health services. These measures include mainly a ban on a number of authorisation and licensing requirements, administrative simplification, the setting up of single points of contact, a list of prohibited requirements (the "black list" of Article 14 – national legislation not permitted) and a list of requirements subject to evaluation (the "grey list" of Article 15 – national legislation has to be justified). The application of some of these provisions - especially the application of Article 15 - to the health sector, including medical services and pharmacy services, could have very negative consequences on the organisation and delivery of the services, and create uncertainty in relation to the principles expressed in article 152 of the EC Treaty. For instance, in the pharmacy sector, the opening of pharmacies is subject to authorisation and/or registration requirements in all Member States. Many countries link the establishment of new pharmacies to the number of inhabitants in a given area or to the characteristics of the territory (e.g. low population density, mountainous areas). The application of such population and geographical criteria has proven to be a key element in the organisation of national healthcare systems, designed to guarantee high quality, accessible pharmacy services throughout the national territory. The ability of Member States to establish this type of requirements would be put at risk by the proposed Directive. In addition, the application of the notification procedure for future requirements, as currently proposed, to health services could be detrimental for the efficient functioning of national health systems and to social security bodies. The responsibility of Member States to organise the delivery of healthcare could be put into question if any measure that appears to be subject to evaluation has to be notified to the Commission. This notification system could lead to situations of legal uncertainty not only for providers and recipients of health services but also for national authorities with competences in the health sector.

- **Free movement of services: principle of country of origin**

In order to resolve restrictions on the free movement of services, the proposal establishes the country of origin principle whereby a service provider who wants to supply services to clients in another Member State would in general be subject only to the rules and regulations of the Member State where he/she is

established. In the view of CPW and of many other health related organisations, in the interest of the patient and to ensure that national health systems continue to work in the most effective way, service providers should always be subject to the rules of the country where the service is provided (host country rule). Consumers in general and particularly patients should not be obliged to research which national legislation is applicable to the provider and what protection is granted by law. Furthermore, the supervision of a service by the Member State of origin does not seem very realistic due to the physical distance between the authorities competent to carry out the controls and the service provider.

Conclusion

These reasons set about above make it clear that as the current Directive is set out, it is inappropriate for healthcare services to be included under the wide-ranging umbrella of such as a general services directive.

In addition, Community Pharmacy Wales believes this Directive to be completely contrary to the direction of policy on community pharmacy for the communities of Wales that has been developed by the National Assembly and the Welsh Assembly Government in recent years in partnership with the profession. The new contract for community pharmacy in Wales is currently being implemented through complex draft Amendment Regulations, specifically for Wales, going through the public process of scrutiny and debate in the National Assembly. Key aspects of this new contract are not compatible with the EU Directive on Services.

Community Pharmacy Wales therefore urges that support is given to the clarification of the Directive such that it does not cover healthcare services of which community pharmacy services are an important part.

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