

Progress made on European services directive, but still much work to do

Monica Alfaro and Colette McCreedy explain the implications of the European internal market services directive for community pharmacy and outline how the Pharmaceutical Group of the European Union has sought to influence the development of this significant piece of legislation

In January 2004, the European Commission put forward a proposal for a directive on services in the internal market. The proposal responded to the need to create at EU level a single market for services, having successfully created a single market for goods. The European economy is increasingly service-based, but most service providers, particularly small to medium-sized enterprises, are currently discouraged from providing services across borders because of administrative and legal barriers at national level. The directive aims to require member states to remove unjustified red tape to encourage cross-border service provision and the freedom of establishment.

The original commission proposal covered all services except financial, transport and electronic communications (covered by existing community legislation) and, thus, included social services such as health care and social care and, of course, pharmacy services.

Implications for community pharmacy

In September 2004, the Pharmaceutical Group of the European Union — community pharmacy's representative body in Europe — adopted a position paper on the commission proposal. The PGEU expressed serious concerns about the application of the proposed directive to the health sector. In particular, it was concerned about the impact of the directive on the ability of member states to organise efficiently the delivery of health services. The most important implications for community pharmacy were that the directive would interfere with governments' abilities to regulate, at national level, laws relating to pharmacy ownership and the establishment of new pharmacies (geographical distribution) or the granting of new contracts to provide pharmacy services (control of entry). There was also concern that pharmacy services provided across borders (ie, by post or via the internet) would operate under the laws in the country of origin of the service rather than in the country of destination of the service. (This is referred to as the "country of origin" principle.)

Lobbying activities:

Since the draft directive was published, the PGEU has worked closely with its members' associations first to analyse closely the proposal and its potential consequences on the community pharmacy sector across Europe, then to agree on a position paper outlining the concerns and the views of the organisa-



tion in relation to the proposal and, lastly, to present the paper to MEPs and to national government representatives.

The PGEU's main strategy was to get health excluded from the scope of the directive. Its argument was that the proposed directive did not sufficiently take into account the specific nature of the health sector. Member states have put in place a number of authorisation schemes and control mechanisms aimed at ensuring that high quality and sustainable health care services are accessible to the public. The application of this directive to health care services would strongly jeopardise the ability of member states to continue to use these types of controls in a flexible and efficient manner.

For instance, in the pharmacy sector, the opening of pharmacies is subject to authorisation or registration requirements, or both, 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 geographical area (eg, 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 health care systems, designed to guarantee high quality, accessible pharmacy services throughout a member state. The ability of member states to establish these controls would be put at risk by the proposed directive. In addition, the application of Article 14.5 would automatically impede the use of economic tests before the opening of a new pharmacy. This means that current control of entry regulations in the UK, which do apply to some extent an economic test, could be prohibited.

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With regard to the so-called "country of origin" principle, the PGEU made the point that, considering the naturally high level of regulation required for health services, it was impractical, to say the least, for a member state to supervise health care services provided by a health care professional established in that member state but provided to patients resident in another member state. In addition to lobbying members of the European Parliament directly, the PGEU also worked closely with other European umbrella organisations representing other stakeholders active in the health sector. As a member of the EU Health Policy Forum (a consultative body representing about 40 European associations active in the health sector set up by the directorate general responsible for health and consumer protection of the European Commission), the PGEU has co-ordinated the work to develop a set of recommendations relevant to the overall issue of health

About the PGEU

The Pharmaceutical Group of the European Union (PGEU) is the European association representing community pharmacists. The PGEU's members are the national professional bodies and pharmacy owners' associations in 30 European countries, including EU member states, EU acceding and candidate countries, and European Free Trade Association members. Through its members, the PGEU represents over 350,000 community pharmacists in Europe.

The PGEU was founded in 1959. Its key objective is to promote at European level the role of community pharmacists as key players in health care and to make sure that the views of the profession are reflected in the EU decision-making process. The association is regularly consulted by EU institutions and EU agencies to gather the views and the input of the community pharmacy profession in relation to specific issues relevant to the sector and to health policy in general. The PGEU meets regularly to analyse developing EU legislation and to develop a common voice at European level.

The UK Delegation of the PGEU comprises representatives of the National Pharmacy Association, the Royal Pharmaceutical Society of Great Britain and the Pharmaceutical Society of Northern Ireland.

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services and the internal market. The recommendations were then endorsed by the whole EU Health Policy Forum. Among other issues, the forum asked for an exclusion of health care services from the scope of the directive.

The UK delegation to the PGEU was particularly active in lobbying UK MEPs, engaging the help of other national pharmacy bodies such as the Pharmaceutical Services Negotiating Committee, the Scottish Pharmaceutical General Council, Community Pharmacy Wales and the Pharmaceutical Contractors Committee in Northern Ireland. Several UK MEPs played a key role in the parliamentary debate. The UK delegation set up meetings with those individuals, as well as with key people within the commission. Making representations to the Government (the Department of Trade and Industry and the Department of Health) was also important, not least because the UK Government was to hold the presidency of the EU in the last part of 2005 and would have a key role in the discussion on the draft directive.

Plenary vote

After two years of work, the European Parliament adopted the first reading report on the proposed directive on services in the internal market on 16 February 2006. There were 391 votes in favour, 213 against and 34 abstentions. The European Parliament has substantially modified essential aspects of the proposal particularly with regard to the scope of the directive and the "country of origin" principle.

The effective action of the different health stakeholders, including the PGEU, has led to a wide majority (434 votes in favour; 207 against and five abstentions) of MEPs supporting the exclusion of health services, confirming what was already expressed by the Internal Market and Consumer Protection Committee (responsible for this proposal) that had voted in November last year.

The co-ordinated action of the PGEU and its members has also resulted in clarification of the concept of health services in terms of the scope of the exclusion from the directive. MEPs have adopted a new recital that clarifies which health services will be considered excluded and refers to health care services and pharmaceutical services provided by professionals to patients. This means there can be no doubt that the intention is to exclude pharmaceutical services from the scope of the directive.

In addition, the controversial "country of origin" principle has been watered down by the EP plenary vote. MEPs are asking for the Directive on Recognition of Professional Qualifications (directive 2005/36) to take preference over the services directive where there is any conflict. Directive 2005/36 provides for specific measures for the establishment and cross-border provision of pharmacy services. Within this directive the "country of destination" principle applies. That means

Why the PGEU is important to UK community pharmacy

The Pharmaceutical Group of the European Union is a forum for information exchange for national pharmacy associations. Through the secretariat, it monitors and analyses the activities of EU institutions in all initiatives relevant to medicines and public health to ensure that the legislative framework supports pharmacists in their final objective of making a major contribution to improving public health.

The PGEU has actively contributed or is currently active on a wide range of issues connected to EU legislative initiatives and policy actions, which are relevant to pharmacy practice and public health in general. In all activities, the PGEU's final objectives are that the legislative framework supports community pharmacists in improving public health through their professional activities and respects the key principle that medicines are special products.

Besides the proposal on services in the internal market, the PGEU has been actively involved in the recent adoption of Directive 2005/36 on the mutual recognition of professional qualifications. For this directive, the PGEU's key objective was to ensure that the high level guarantees provided by the existing directives ensuring free movement of pharmacists were not jeopardised. The PGEU also asked and obtained (in first reading) the introduction of a clear reference in the directive to the importance of continuous training for pharmacists.

In another important issue for the pharmacy sector — the pharmaceutical review — the PGEU has closely followed the discussion relevant to the revision of the patient information leaflet and issues relevant to labelling requirements and advertising. Also, for all these issues the PGEU has collaborated closely with other European associations representing other health professionals or health-related national government organisations.

The PGEU has a well-developed network of contacts in the European institutions and it is generally consulted before official proposals for new legislation are presented.

anyone established in one member state and providing services in another must comply with the legislation within the member state in which the services are provided.

Where do we go from here?

The plenary vote of the European Parliament concludes the first stage of the legislative procedure which is the first reading at the EP. Now the proposal as amended by the EP will be forwarded to the Council of Ministers and the European Commission. The commission will have to prepare a modified proposal taking on board and adapting the EP requests. Commission representatives, including commission president José Manuel Barroso and internal market commissioner Charlie McCreevy, have stated on several occasions that they will respect the will of the EP and accept those amendments that have been supported by a majority of MEPs. Therefore, the commission is not likely to reintroduce health services in the text of the proposal. However, it will have to invest some time in making workable the changes introduced to the article covering the "country of origin" principle. It appears that the commission wants to have the modified proposal ready in time for the council European summit on 21 and 22 March. Previously, the commission had said that the proposal would be ready for April or May, so things are moving more quickly.

In preparing its modified proposal, the commission will attempt to produce a text on which the Council of Ministers can quickly reach political agreement and adopt as a Council Common Position before the summer break.

Member states are generally in favour of the adoption of the proposed directive and consider it necessary to boost the European economy. The maintenance of the "country of origin" principle other than for health services is essential for some countries in

order to make the directive work in practice. Six more liberal-minded member states (UK, Spain, Netherlands, Poland, Hungary and the Czech Republic) recently wrote to the commission to warn against any significant watering down of the text. However, regarding the exclusion of health, there is a general support among member states to exclude both private and public health services.

If all Parliament amendments are acceptable to the Council, the legislation will be adopted in its modified form. If the Council rejects any of the EP amendments or adds any of its own (this is more likely to happen), the text will then return to the EP for a second reading. Due to the controversial nature of this proposal, anything could happen and it is difficult to predict when the final adoption will take place. If no agreement is reached, the proposal could be blocked at Council for years. Also, if the Council position differs very much from that of the EP, it may be necessary to convene the "Conciliation Committee" and there will be no guarantee that a final agreement between these two institutions will be reached.

So there is still much work to do. The PGEU and the UK delegation will continue to monitor developments carefully and be ready to influence progress where necessary.

The most important outcome for community pharmacy will be if, in the final text, health remains excluded from the scope of the directive and pharmaceutical services included in the definition of health services. This will be a victory not only for this directive but for the way in which community pharmacy is regarded generally at European level. For many years, there has been a debate within the Commission about whether community pharmacy services are classed as health or retail services. The adoption of the EP's proposal for the services directive will settle the argument.