



CEPLIS TELEGRAM

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The European Court of Justice has recognised the right of Member States to restrict the ownership and management of pharmacies to pharmacists only

On the 19th of last May the European Court of Justice (ECJ) has rendered public a judgement relating to the ownership and the management of pharmacies. In this judgement, the Court has recognised the right of competent authorities in Member States to adopt regulations restricting the ownership of pharmacies to pharmacists only.

The ECJ has in fact deliberated on three litigations: 1) *Commission vs. Italy* (C-531/06); 2 and 3) joined cases *Apothekerkammer des Saarlandes and Others* (C-171/07 and C –172/07).

In the case of C-531/06 the European Commission has brought Italy before the Court for two legal regimes (law No 362 of 8 November 1991 and No 475 of 2 April 1968) that have for consequence to restrict the ownership of pharmacies to pharmacists

only. According to the Commission, the Italian Republic has failed to fulfil its obligations under Community law.

The Joined Cases, *Apothekerkammer des Saarlandes and Others*, C-171/07 and C – 172/07, concern the authorisation that had been granted by the competent ministry in Saarland (Germany) to DocMorris, a Dutch company, entitling it to operate a branch pharmacy in Saarbrücken starting July 1st, 2006. The Ministry's decision was challenged before the Administrative Court of Saarland by several pharmacists and their professional associations, on the ground that it was not consistent with German legislation which restricts the ownership and operation of pharmacies exclusively to pharmacists.



The company in question claimed that the German legislation on this issue constitutes a violation of two major European principles: the freedom of movement of capital and the freedom of establishment.

The ECJ has used several arguments in order to recognise the right of Member States to restrict the ownership and management of pharmacies:

- Competent authorities have responded that **limitations were necessary to ensure the provision of medical products of good quality to the public.** The Court has also added in its statement: “Where there is uncertainty as to the existence or extent of risks to human health, it is important that a Member State should be able to take protective measures without waiting until the reality of those risks becomes fully apparent. Furthermore, a Member State may take measures that reduce, as far as possible, a public-health risk, including, more specifically, a risk to the reliability and quality of the provision of medicinal products to the public.”
- As you know, legislation on health-related issues falls under the subsidiary principle and is thus the privilege of member States. According to the Court, **Member States are allowed to take any discretionary action in order to ensure the quality of healthcare-related products that are sold to the public.** In this case, the Court has accepted that a Member State can use its legislation to restrict the ownership and management of pharmacies to pharmacists alone. Indeed, several Member States have estimated that the risk for public health involved in granting non pharmacists the right to sell such products was important enough to impose such a restriction.
- The Court considered that competent authorities adopting such limitations are based on the fact that **products sold in pharmacies have a therapeutic effect unlike ordinary products. This presumes that if the products in question are taken incorrectly they may cause serious damage to a person's health. The Court has taken also into account the asymmetry of information between the health professional and the patient, and the need**

of the latter to receive full information on the products he/she purchases, thus stressing the need for the owner of a pharmacy to be properly trained to assume such a task.

- The Court has also recognized that a **pharmacists obligation to abide by ethical codes can temper the necessities arising from unning a pharmacy with only financial objectives**: *“a pharmacist by profession, is presumed to operate the pharmacy not with a purely economic objective, but also from a professional viewpoint. His/her private interest connected with the making of a profit is thus tempered by his/her training, by his/her professional experience and by the responsibility which he owes, given that any breach of the rules of law or professional conduct undermines not only the value of his/her investment but also his/her own professional existence”*, according to the Court. Non pharmacists cannot provide the same safeguards than health professionals.

At the same time, the Court has dismissed the action of the European Commission against Italy *for failure to fulfil obligation*. **The Court has considered as justified the limitations of Italian authorities to “undertakings engaged in the distribution of pharmaceutical products from taking stakes in municipal pharmacies”.**

The Court has concluded, in its judgement, that *the “freedom of establishment and the free movement of capital do not preclude national legislation which prevents persons not having the status of pharmacist from owning and operating pharmacies.”*

For further information on the Court judgement on these two cases, please visit the Website of the European Court of Justice’s website ([Apothekerkammer des Saarlandes and Others](#) and [Commission vs. Italy](#)), or contact our CEPLIS Secretariat.

Priorities of the Swedish Presidency

As you know, starting on 1st of July until the end of the year 2009, the European Council will be chaired by the Kingdom of Sweden. Under the Treaty of Nice in fact, the Presidency of the Council rotates between the Member States on a half-yearly basis. The country presiding over the Council functions as the driving force in the EU's legislative and political decision-making process. The Swedish authorities have already issued several statement indicating the priorities of their country’s Presidency.

Addressing a seminar of the very influential Brussels Think Tank “Centre for European Policy Studies”, **Mr. Fredrik Reinfeldt, Prime Minister of Sweden** has identified **“Managing the financial crisis and unemployment and addressing climate change – (as) the two main priorities of the Swedish Presidency.”**

Besides these two main priorities, the Swedish Prime Minister has also mentioned a number of other important issues that his country intends to pursue during the next six months. These include **judicial cooperation under the Stockholm Programme – a**

following up of the Hague Programme which includes police and customs cooperation, rescue services, criminal and civil law cooperation, asylum, migration, visas and checks at external borders, etc.

A Baltic Sea Strategy is also high on the Swedish agenda aiming at improving the environment in the Baltic Sea and at strengthening the region's competitiveness and integration in the EU. The Prime Minister has also underlined the negotiations of accession with Croatia and Turkey, and has emphasised that progress will chiefly depend on the efforts made by the two countries.



Mr. Frederick Reinfeld, Prime Minister of Sweden and Mr. Jose Manuel Barroso, President of the European Commission

The following are the main points the coming Presidency is promising to work on :

- **Environment:** there are four priority issues - the climate, an eco-efficient economy, biodiversity and the marine environment.
- **General affairs and external relations:** Sweden shall attach great importance to ongoing EU missions and shall maintain good preparedness for unexpected events.
- **Justice and home affairs:** the Stockholm Programme is to define the framework for EU police and customs cooperation, rescue services, criminal and civil law cooperation, asylum, migration and visa policy for the period 2010–2014.
- **Employment, Social Policy, Health and Consumer Affairs. EMPLOYMENT:** the EU must take measures to reduce the negative effects of the ongoing crisis on employment and at the same time address future challenges resulting from an ageing population. **HEALTH:** the Presidency will take up the experience of 'new influenza' and how the EU and its member States can move forward in their work on good preparedness. The Swedish Presidency will continue to pursue negotiations on proposals put forward by the European Commission in July 2008, concerning the right of patients to receive healthcare in other EU member States and the struggle to enhance dignity and quality of life for elderly persons in Europe.
- **COMPETITIVENESS:** the Swedish Presidency will promote long-term sustainable growth through a transition to an eco-efficient economy.

- **TRANSPORT, TELECOMMUNICATION AND ENERGY:** the accent will be here on eco-efficiency.
- **FISHERIES, FOOD AND ANIMAL WELFARE:** There will be three priority issues in the area of agriculture and fisheries. One is fisheries where Sweden will initiate the debate on the future shaping of the policy on this field. The second involves food and climate, where two of the major global challenges are managing the impact of agriculture on climate and the impact of climate change on agriculture, whilst securing global food supply. The third concerns sound animal husbandry and healthy animals.
- **EDUCATION, YOUTH AND CULTURE,** Promoting a creative generation - children and young people in the new culture and media landscape

For further information, please visit the Website of the Swedish Presidency (<http://www.se2009.eu/en>).

The European Commission brings France before the European Court of Justice on the issue of ownership of medical laboratories

As you know, the “Syndicat des Biologistes” [1] (SDB) has reached out to CEPLIS’ members in order to seek for support in the infringement procedure initiated in January by the European Commission against France for non compliance of the French rules on the ownership of the capital of biomedical laboratories. with the freedom of establishment guaranteed by Article 43 of the EC Treaty.

Like in the case of the ownership of pharmacies where the Court has legitimated legal restrictions on establishment imposed by Member States in cases where public health interests could be at stake, the French biologists strongly believe that the capital of biomedical laboratories cannot be entirely left to financial interest.

In France in fact, the practitioners of medical biology are recognized as a health-related medical profession with direct contact and important influence on patients' lives. Leaving the ownership of medical laboratories to non-professionals with solely financial objectives may lower the quality of analysis and of services to the patient. Many European States that recently accepted looser rules on capital ownership of biomedical laboratories are currently facing problems of professional devaluation, with a rise of “mega laboratories” in both public and private care sectors and a decrease in quality of service to patients.

An unfavourable decision of the Court on the French case may well put the role and place of all European liberal professions – and this not only in the healthcare sector - into question. In this context, both CEPLIS and the SDB

believe that the European authorities should respect the added value of liberal professions in Europe, based primarily on high quality of services to patients and clients through respect for strict ethical rules and independence. As such, the services of these professions should not be evaluated by market economy benchmarks.

In that context, CEPLIS and the SDB ask the European Commission to reconsider its arguments on the French biomedical laboratories case and call upon other Member States to support France, like Spain, Latvia, Greece and Austria did in the pharmacy case.

For further information on the case, please do not hesitate to contact Anne-Juliette Rohrbach (Anne-Juliette.Rohrbach@nextep.fr), Sébastien Faure (sebastien.faure@nextep.fr) or the CEPLIS Secretariat (ceplis@scarlet.be)

[1] The representative voice of the pharmacy biologist practitioners in France - chaired by Mr. Jean Benoit.

[2] See : Joint cases C-171/07 et C-172/07

News from our members

The **Nursing and Midwifery Council of the United Kingdom (NMC)**, a correspondent organisation of CEPLIS, is a regulatory body aiming at safeguarding the health and well-being of the public by ensuring nurses and midwives consistently deliver high quality healthcare. A few months ago, the NMC has invested a new President and Executive Board for a three years term. Its new Chairman, **Professor Tony Hazell** is the first non-nurse President of this body appointed for a full term.

Professor Hazell has significant experience at both executive and board level in a variety of organisations. He held the post of Assistant Principal at the University of Wales Institute Cardiff (UWIC), where he spent 12 years as a member of the Academic Board and six years as an elected member of the Board of Governors. From 1991-1995 he served as a member of the UK Central Council for the Education and Training of Social Workers (CCETSW), chairing the organisation's Welsh Committee from 1992-1995. He was a member of the governing body of the South Wales Institute of Nursing and Midwifery Education and has continued work closely with what is now the School of Nursing and Midwifery Education at Cardiff University.

Professor Hazell has also served as a lay member of the Health Professions Council (HPC) between 2002 and 2008.

Conferences and events to come

EESC debates its Programme for Europe in Rome, organised by the European Economic and Social Committee

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