



## ***European Association of Hospital Pharmacists***



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## I. Spain loses EU court case on access to hospital pharmacy practice

Source: European Court of Justice (ECJ)



In 2007, The Commission decided to refer Spain to the European Court of Justice over its failure to implement Directive 89/48/EEC on a general system for the recognition of professional qualifications in the case of the profession of hospital pharmacist (ECJ case C-39/07).

Directive 89/48/EEC is designed to ensure freedom of movement within the Union for a large number of regulated professions. Spain decided to implement this Directive by means of a decree applicable to all the regulated professions listed exhaustively therein. However, the profession of hospital pharmacist, although regulated in Spain, was not included in the decree.

Spain argued that since the specialisation is not part of this Directive, it falls out of its scope, whereas the European Commission argued otherwise, stating that, specialist pharmacy qualifications, such as those relating to hospital pharmacists, are covered by the directives on the general system for the recognition of professional qualifications, such as Directive 89/48/EEC.

Qualified hospital pharmacists from other EU Member States have difficulties in obtaining the right to practise in Spain and, consequently, are denied the rights of freedom of movement and freedom of establishment granted by the Treaty, the ECJ rules.

More information and the full court text:

<http://curia.europa.eu/jurisp>

## II. New EU - US agreement on medicines

Source: European Commission



The Transatlantic Economic Council (TEC) is a political body to oversee and accelerate government-to-government cooperation with the aim of advancing economic integration between the European Union and the United States of America.

At the 13th May TEC, the following specific priority projects have been agreed:

1. The Commission/EMA and the Federal Drug Administration (FDA) will pilot joint inspections of companies manufacturing pharmaceuticals in the U.S. and in the EU and of companies manufacturing active pharmaceutical ingredients in third countries.
2. The Commission/EMA and the FDA will pilot the exchange of inspection schedules, results, and information on inspected manufacturing sites in order to attain more Good Manufacturing Practices (GMP) inspection coverage collectively and to better

identify manufacturing sites producing active pharmaceutical ingredients in third countries.

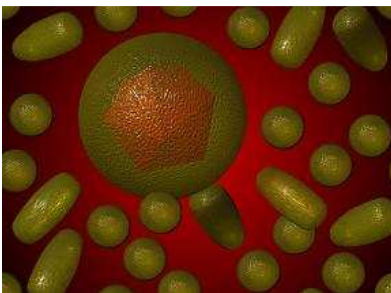
3. The Commission/EMA and the FDA will step up collaboration to determine to what extent dedicated production facilities are necessary for certain pharmaceuticals taking into account a risk based approach. Subsequently, it is expected that a revised EU guideline will be published for public consultation in the first quarter of 2009. The FDA is also in the process of clarifying this issue through proposing amendments to existing regulations and drafting guidances that are in the process for issuance.
4. The EMA and the FDA have recently announced successes in their transatlantic work on biomarker development and validation for various product development purposes. Both parties will continue to work on this initiative with further biomarker development and validation.

More information:

[http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/new\\_en.htm](http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/new_en.htm)

### III. MEPs call for more EU action to tackle hepatitis

*Source:* European Commission



Members of the European Parliament and health organisations have called for action to encourage better data collection and surveillance of the world's "silent killer" hepatitis.

"It is important to show people that Hepatitis B and C are preventable, detectable, curable and treatable," said the German European People's Party (EPP) deputy

Thomas Ulmer during a discussion on Tuesday organised by the European Liver Patients' Association (ELPA) to mark this year's World Hepatitis Day.

The debate saw the launch of the "Am I number 12" campaign, a series of 12 political "asks" made on behalf of patient and professional organisations.

One in 12 people are infected with a virus responsible for chronic viral hepatitis, and the vast majority are unaware that they could be in danger from what ELPA and other liver groups are calling a "silent killer".

It is estimated that around 500 million people in the world are infected with either hepatitis B or C.

The demands or "asks" include the adoption of a council recommendation on targeted screening for viral hepatitis across Europe, support for EU-funded research in this field and a commitment to an EU strategy to protect healthcare workers from blood-borne diseases.

During the lunchtime debate, UK Labour deputy Neena Gill questioned whether more legislation at the national level was really necessary.

“The more legislation there is, the more time medical practitioners spend filling in forms and less time getting on with the job of actually curing people,” she said.

“There is a degree of resistance from practitioners to more legislation,” she added.

Marita van der Laar, of the European centre for disease prevention and control (ECDC), also added that although greater awareness was necessary, it was important to encourage effective rather than excessive legislation in Member States.

“By giving guidance to Member States in setting up targeted screening measures for risk groups and raising awareness of the disease, such a recommendation could make a real difference to patients across Europe.”

#### **IV. EU needs to be a better place for researchers**

*Source:* European Commission



Planned partnership between EU countries should make Europe a more attractive place for researchers.

Europe may produce more science and engineering graduates than either the US or Japan, but it doesn't manage to keep them. Its meagre share of graduate researchers in the workplace is a cause for concern, especially as Europe is trying to develop its knowledge-based economy.

The main problems are that:

1. in many EU countries, there is little public-sector recruitment through competitive examination,
2. young researchers mostly rely on short-term contracts,
3. climbing the career ladder is based more on seniority than performance,
4. traditional, academic training is poor preparation for the needs of the modern economy.

To redress this, the EU proposes working in partnership with Member governments to encourage more open recruitment, greater social security and pension cover for researchers abroad, better employment and working conditions and increased access to training.

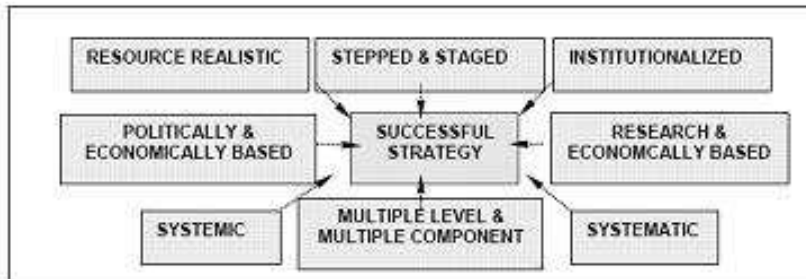
The EU's research commissioner, Mr Potočník, spoke of his vision for a "fifth freedom" in Europe – knowledge – to allow students, scientists and academics to take advantage of the European job market rather than having to look elsewhere or switch careers.

The 2007 public consultation "The European research area: new perspectives " showed that creating an attractive Europe-wide job market for researchers should be a top priority. More than 80% of respondents said they supported the idea of a partnership

between the EU and its Member governments to guarantee coordinated, efficient and coherent use of legal and financial tools and resources.

## V. Guidance on developing quality and safety strategies with a health system approach

Source: WHO



The World Health Organisation (WHO) Europe launched in May 2008 its publication entitled "Guidance on developing quality and safety strategies with a

health system approach".

A balanced integration of health system functions is critical to efficiently addressing the evolving issue of quality and safety at the national level. This publication aims to provide guidance for Member States on promoting the quality and safety agenda. It covers the whole process of developing national quality and safety strategies, while taking into consideration varied local circumstances.

Quality and safety have long been recognised as key issues in establishing and delivering accessible, effective and responsive health systems, however dedicated national interventions have often been based on different perceptions on quality, which together with the current variety of health systems' development and sophistication have resulted in uneven quality requirements and health care performance across Europe.

The Guidance builds on several other dedicated documents and initiatives from WHO/Europe, within the developing and evolving health systems framework.

The full document is available here: <http://www.euro.who.int/Document/E91317.pdf>

## VI. Outcome of EU Consultation on key elements of a legal proposal on information to patients

Source: European Commission DG Enterprise and Industry

Directorate General Enterprise and Industry conducted a public consultation between 5 February and 7 April 2008 on the key ideas of a legal proposal in which the official aim was to ensure that all EU citizens have access to good-quality, objective, reliable and non-promotional information on prescription-only medicinal products. It published the result of the consultation in May 2008.

There was an overall consensus that there is a need to provide citizens of EU Member States with understandable, objective, high-quality and non-promotional information about the benefits and the risks of their prescription-only medicines. The great majority of the respondents had a view that the ban on direct-to-consumer advertising of prescription-only medicines should be maintained, making sure that there is a clear

distinction between advertising and non-promotional information. However, it was agreed that such a distinction is not easy to establish.



Almost half (48%) of the respondents had a view that the pharmaceutical industry is not an appropriate source of prescription-only medicine information in general, mainly because there may be a conflict of interest relating to the financial interests. The payers (social institute organisations) and healthcare professionals were mostly suspicious, while responses from media and patient information organisations and pharmaceutical industry mostly supported pharmaceutical companies as information providers. Some (14%) of the contributors had a view that if there would be a clear distinction between advertising and information, pharmaceutical

companies would be a valuable source of prescription-only medicine information, because they know the product.

Among the responses, only seven per cent supported TV and radio as channels to disseminate information about prescription-only medicines (Table 3). A majority (36%) of the contributors – including the pharmaceutical industry – did not support TV and radio. According to their opinions, TV and radio would not be suitable channels because of the nature of the media. Information that passively comes to the patient, for example by TV and radio, would not be beneficial for the individual patient. Consumer and patient organisations highlighted the difficulties to make a distinction between advertising and information and the possibility to misuse TV and radio in information provision.

#### **The outcome of the consultation (summary):**

[http://ec.europa.eu/enterprise/pharmaceuticals/patients/docs/summary\\_public\\_cons\\_220508.pdf](http://ec.europa.eu/enterprise/pharmaceuticals/patients/docs/summary_public_cons_220508.pdf)

#### **All responses:**

[http://ec.europa.eu/enterprise/pharmaceuticals/patients/patients\\_responses\\_200805.htm](http://ec.europa.eu/enterprise/pharmaceuticals/patients/patients_responses_200805.htm)

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*Comments and suggestions are welcome: [ed@eahp.eu](mailto:ed@eahp.eu)*

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