



European Association of Hospital Pharmacists



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The next issue of the EAHP EU monitor will be released in September 2009, have a very pleasant summer!

I. Information on Clinical Trials to be made public

Source: EMEA & EPHA



Information on all clinical trials in Europe and paediatric trials undertaken worldwide are to be made public. The EudraCT database, hosted by the European Medicines Agency (EMA) will make all data related to the application for authorisation and progress of all

clinical trials taking place in Europe open to the public, by November 2009. This public information is a breakthrough for freedom of information and for greater transparency of the clinical trial process.

The EMA carried out a survey to find out which aspects of clinical trial information are of most interest, how people might use this information and how they will want to access it. This research will help the EMA to design a website appropriate to the needs of the public and other interested parties.

The EudraCT database, a database of all clinical trials in Europe, is hosted and run by the EMA. In its current form, the data is only available to competent authorities (Member State authorities responsible for authorising clinical trials in their country) as the aim of the database is to increase data sharing and coordination between Member States. However, new legislation means that in the latest update of EudraCT, the information will be made publicly available.

EudraCT database Version 7 went online in June 2009. The updated version of EudraCT has three new functionalities that attempt to make the life of the sponsors (those companies or research facilities sponsoring the clinical trial) easier. Version 8 which is now in production and will go online in November 2009 will make data available to the public.

The public part of the database will bring all data on clinical trials happening in Europe together in one place. It will include trials of products that do not have marketing authorisation and any third country trials that form part of a Paediatric Investigation Plan (PIP) (a PIP is a way of collating all data relating to trials on children and ensuring that the reformulation of the products for children is documented).

The decision of the Competent Authority and/or the opinion of the Ethics Committee will automatically be made public for each clinical trial as soon as this information is recorded in EudraCT.

Version 9 will be available in September/October 2010. Where the EudraCT database has so far included information on the application to conduct clinical trials, version 9 will include more functions based around the publication of the results of clinical trials.

Currently there are 19,219 distinct clinical intervention trials of medicinal products with one investigator site in the EU in the database.

II. Patient rights to cross-border care debated at the Council



On 9 June 2009, informed by a Presidential progress report and questions suggested by the Presidency, the Council (representatives and heads of Member States) held a public debate on the draft directive concerning the application of patients' rights in cross-border healthcare.

Ministers welcomed the general direction the discussions are taking, and in particular the restructuring of the text, the clarification of the responsibilities of the Member States and prior authorisation.

Many ministers wished to exclude long-term care from the scope of the draft directive, which was agreed by Commissioner for Health Androulla Vassiliou. As regards the scope of the draft directive, views differ on whether it should be limited only to healthcare providers contracted to public health insurance or otherwise recognised by the public system, or also be extended to private healthcare providers not thus far acknowledged.

She suggested further discussions however on prior authorisation and the possible exclusion of some healthcare providers.

Her counterpart, the President of the Council, concluded the debate by stressing the need for prior authorisation under certain conditions, as long as the relevant case law of the European Court of Justice is respected. With regard to the scope of the draft directive, the Presidency suggested that quality and safety standards might be used as criteria to decide which healthcare providers are covered. The reimbursement of prescriptions, the provisions on cooperation on healthcare and the legal basis of the draft directive will also be the subject of further discussions of the Council and the European Parliament.

The new positions helped create some common ground with regard to other parts of the proposal, e.g. the extent of the codification of European Court of Justice case law, the exclusion of certain types of care from the scope of the directive, mutual recognition of prescriptions and cooperation on healthcare.

Work on this file will continue under the incoming Swedish Presidency.

During this Council meeting, the ministers also adopted a recommendation on patient safety, including the prevention and control of healthcare-associated infections (See EUM issue 30 "<http://www.eahp.eu/EAHP-EU-Monitor/EU-Member-States-to-adopt-strategy-for-patient-safety>"). The recommendation aims to create a framework to stimulate policy development and future action in and between Member States to address key patient safety issues.

A further recommendation on action in the field of rare diseases was accepted during the meeting. This recommendation aims to provide a coordinated EU approach to ensure effective recognition, prevention, diagnosis, treatment, care and research in the field of rare diseases in Europe.

III. European Council discusses the pharmaceutical package.

Source: European Council & EPHA



During the last Health Council meeting (8 and 9 June 2009), Member States reviewed the three pieces of legislation forming the “pharmaceutical package”: fighting counterfeiting, European pharmacovigilance and information to patients.

With regard to preventing falsified medicinal products from entering the legal supply chain, ministers broadly welcomed the proposal, highlighting the importance of the draft directive on the safety of medicinal products. However, individual elements of the proposal need further discussion. This concerns in particular definitions e.g. of "falsified medicinal products", the scope of the proposal and the safety features.

Concerning pharmacovigilance ministers warmly welcomed the Commission proposals for regulation and a directive, and highlighted their contribution to the protection of patients. No agreement has been found yet on the composition, role and mandate of the proposed Pharmacovigilance Committee and its interaction with other preparatory bodies of the European Medicines Agency (EMA).

Many ministers expressed their concerns over the regulation and directive on the provision of information on medicines by marketing authorisation holders. While agreeing that there is a need to improve the information to the general public on prescription-only medicinal products, many delegations fear that the suggested system will be overly burdensome for competent authorities without leading to significant improvements in the quality of the information provided to patients. In addition, many delegations hold that the distinction between "information" and "advertising" is not sufficiently clear. So they fear that the proposals will not provide adequate guarantees, and that the prohibition of advertising of prescription-only medicinal products to the general public will be circumvented.

Health-related and patient associations, in parallel with the Council discussions, are also debating the question of information to patients. A wide range of organisations representing key healthcare stakeholders – patient groups, family and consumer bodies, social security systems and health professionals – met on 2 June 2009 to discuss the European Commission’s proposed Directive. They highlighted the need for relevant health information, as a fundamental part of healthcare, centred on patient and consumer needs as well as public health priorities, and provided by reliable independent sources.

Participants called upon the European Commission to work on a new and more ambitious strategy, truly recognising the legitimacy of patients and their family circle, patient organisations, consumers, users and their organisations as real partners on the process.

They proposed key elements requiring attention, such as:

- improving the readability of the packaging and the patient information leaflet (better enforcement of article 59 of Directive 2001/83/EC modified by Directive 2004/27/CE);
- optimising communication between patients and health professionals;

- encouraging national health authorities to become proactive and more transparent providers of information on the efficacy and safety of medicines;
- developing and sustaining existing sources of comparative information that help patients weigh up the pros and cons of existing treatments in order to participate in informed treatment choices.

IV. European call to move medicines to Health Directorate General (DG SANCO)



One of the key issues for the public health community is the question of pharmaceutical policy. Although pharmaceuticals form an integral part of health policy, they are dealt with at the European Commission level within the Enterprise Directorate General (DG). Those active in the public health community, consumer organisations, health insurers, etc, have been pointing out this anomaly for a long time. These organisations – including EAHP - are now advocating a switch of competency in pharmaceutical policy, which should be the responsibility of the European Commissioner dealing with health policy and be managed within a health-focused Directorate General.

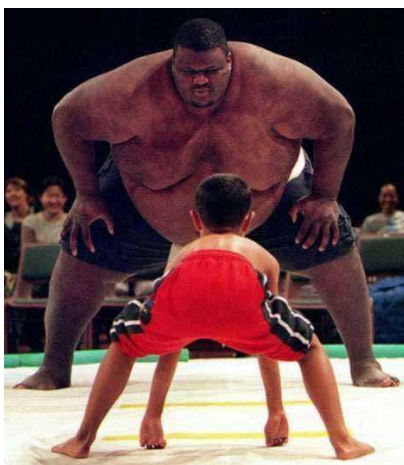
A large number of European health associations signed an open letter on 17 June 2009 (see attached) and sent it to Member States' health representatives, the European Commission and Members of the European Parliament; this letter starts a campaign for the transfer of competence on pharmaceuticals from the Commission's Directorate General (DG) Enterprise & Industry to DG public health (SANCO).

The campaign starts as the negotiations have been launched over the shape of the European Commission and the allocation of posts among Commissioners and will take several months.

A transfer of competence would bring the European decision makers much more closely in line with the way that national governments view and manage pharmaceutical policy.

V. Pharmaceutical companies facing anti-trust probe

Source: European Voice



On 8 July 2009 the European Commission opened an anti-trust investigation into six pharmaceutical companies and indicated that further action could follow, after an inquiry into the industry found evidence of anti-competitive practices.

The six companies are: Les Laboratoires Servier, a French company that manufactures new drugs, Krka d.d., Lupin Limited, Matrix Laboratories Limited, Niche Generics Limited and Teva UK Limited (all five making generic copies). The Commission suspects that Servier and the generic companies of reaching deals that hinder generic copies of a heart medicine

developed by Servier getting onto the market.

The Commission stressed that the investigation has not proved that the companies have broken the rules and that it is also looking at other companies, including the international giant GSK.

The announcement came at the end of an 18-month inquiry into competition in the pharmaceutical industry, launched in January 2008 with a number of dawn raids on some of Europe's biggest drug companies.

In the final report, published on 8 July 2009 the Commission concluded that market entry of generic drugs has been delayed as a result of company practices.

Consumers had to wait seven months after patents had expired until cheaper generic medicines came onto the market, according to a sample of medicines that the Commission studied in 17 Member States. Consumers and taxpayers could have saved €3 billion between 2000 and 2007 if the medicines had come onto the market immediately.

However, the Commission also said that shortcomings in the regulatory regime could not be excluded as part of the cause for delays.

The commission said that the inquiry showed the need for a single community patent and patent litigation system. The European Federation of Pharmaceutical Industries and Associations (EFPIA), which represents originator companies, insisted that the Commission had failed to substantiate earlier allegations that patenting strategies dampened innovation and delayed generics illegally.

All parts of the industry welcomed moves to speed up the creation of a community patent system, a goal that the EU has struggled with for more than 20 years.

Suzanne Rab, a lawyer at Hogan and Hartson who represented an originator company in the sector inquiry, said that the Commission's approach suggested it would pursue individual infringement cases, rather than draw up guidelines on competition law. She argued that "a consolidated statement of the legal framework" would be preferable to letting the law "develop ad hoc".

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Comments and suggestions are welcome: ed@eahp.eu

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