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This Newsletter is intended to provide general information on the members of conférence bleue and on recent developments of relevance to the pharmaceutical sector. The information and opinions which it contains are not intended to provide legal advice, and should not be treated as a substitute for specific advice concerning particular situations.

# Insights

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## New finnish medicines agency established

Hanna Paloheimo, Castrén & Snellman Attorneys, Helsinki

The Parliament of Finland passed an amendment to the Medicines Act on 16 October 2009, establishing a new Finnish Medicines Agency (FIMEA) that started to work on 1 November 2009. The new agency's location is Kuopio, a town in Eastern Finland.

The Finnish Medicines Agency will be built on the National Agency for Medicines (NAM) and the National Agency for Medicines will be closed down when the new agency starts work. The main tasks of the FIMEA will include authorisation and supervision in the pharmaceuticals field, research and development as well as the production and dissemination of information on medical products. One of the goals is also to improve the effectiveness of pharmaceutical services and pharmacotherapy.

The new agency's tasks will include most of the present tasks of the National Agency for Medicines. However, as of 1 November 2009, the monitoring of the manufacture and marketing of medical devices and the promotion of their safe use will be transferred to the National Supervisory Authority for Welfare and Health (Valvira). In addition, though the present National Agency for Medicines has already worked actively on issues relating the supervision of medicinal products within the European Union, the new Medicines Act emphasises and expands the importance of the EU dimension and international cooperation in the FIMEA's work.

The establishment of the FIMEA will be carried out during a transition period of five years. Different operations of the former National Agency for Medicines will be transferred to the FIMEA in Kuopio in stages, and the transition will be completed by the year 2014. The Ministry of Social Affairs and Health and the National Agency for Medicines has prepared a plan to ensure the optimal functioning of the operations and to retain skills and expertise during the transition process.

Several reasons for the reorganisation of pharmaceutical services in Finland have been stated. The most important ones are the desire to improve pharmaceutical therapies, the ageing of the population and the increased costs of pharmacotherapy.

Finnish Chancellor of Justice Jaakko Jonkka has criticised the preparation of the legislative proposal regarding the Finnish Medicines Agency. Jonkka notes that the time spent on the preparation of the reorganisation was too short. For example, interest groups had only a few days time to comment on the draft of the Government Bill regarding the new agency. Jonkka also noted that the decision of the Ministry of Social Affairs and Health regarding the location of the new Agency was inadequate and even misleading.

### **Orphan medicinal products**

**Maria de Lourdes Lopes Dias, Lopes Dias & Associados, Lisbon**

Medicinal products for rare diseases - called "orphan" medicinal products - are medicines intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions that affect no more than five in 10,000 people in the European Union. The situation is of great importance because these medicines, for economic reasons, would be unlikely to be developed by the pharmaceutical industry without incentives. Because of the high number of rare pathologies, this situation has been identified as a priority area for European Community action. As a consequence, international, European and national measures have been adopted.

In Portugal we estimate that there are between five to eight thousand rare diseases and 600 to 800 thousand patients. There is a big problem involving medicines for rare diseases according to the patient's needs, and the fact that pharmaceutical industry does not develop that kind of medicines. The truth is that patients with rare diseases suffer a lot with wrong and late diagnosis, most of the studies are very lengthy, there is information missing, many difficulties for health professionals and no research and innovation. According to the European Organization for Rare Diseases – EURODIS - which represents more than 350 rare disease organizations in 39 countries, covering more than 1,000 rare diseases, the time to wait for a correct diagnosis is five to twenty years. There is also ORPHANET, which is a data base dealing with rare diseases and contains information about more than 3.600 diseases. These patients have now some help regarding information of their diseases and support of many kinds.

In Portugal some innovations regarding rare diseases and medicinal products for this purpose were developed: we have a National Association of Rare and Mental Retardation named RARÍSSIMAS, which has been supporting many families with members suffering rare diseases. A National Program of Rare Diseases – PNDR – was presented and approved by the Health Ministry in November of 2008. This program is to be implemented until 2015. However, patients are claiming for faster measures.

A Portuguese Alliance of Associations of Rare Diseases was also created, which congregates nine national associations, a National Register of Rare Diseases and a special card for these patients, which was approved on 7th May 2009. This card will provide to these patients a different and a special access to health services in general and in emergency situations. The card will have a chip with all the specific information regarding the patient and his diagnosis. The Government will ask the National Commission of Data Protection to be informed every six month regarding the system of these cards, register and the circulation of information in the National Health System (SNS). It was announced that Health Centers for treatment of these diseases will also be created. There are important

advantages of all these measures, not only for the patients, but also for the services and health professionals.

However, with all these innovations – a National Register of Rare Disease, a Special Card for Patients with Rare Diseases, a National Program for Rare Disease (PNDR), a Portuguese Alliance of Rare Diseases and also Raríssimas – the truth is that the pharmaceutical industry does not invest and does not develop the needed medicinal products for rare pathologies. The EU created some incentives for the development of orphan medicines, which resulted, since 2005, on the duplication of the number of medicines with the designation of “orphan” medicines, according to the Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16th December 1999.

The problem is that the development of orphan medicines will not be recovered by the expected sales of this medicinal product; the pharmaceutical industry would be unwilling to develop the medicinal product under normal market conditions. On the other hand, patients suffering from rare conditions should be entitled to the same quality of treatment of other patients; it is therefore necessary to stimulate the research, development and introduction into the market of appropriate medicines by the pharmaceutical industry. Fortunately, as said, this situation has been changed with some incentives created by the EU. However, some of these medicines have already the designation of orphan medicines but do not have the marketing authorization (AIM) in order to be commercialized as EU Governments take much longer time to deliver them. Member States and the EC must provide incentives for the research, development and introduction into the market of designated orphan medicinal products.

The European Commission Communication and Council Recommendation on Rare Diseases dated of June 9th 2009 calls upon Member States to implement national plans for rare diseases before the end of 2012. The EU calls the attention to the importance to ensure that rare diseases are adequately coded and classified, that there will be Centers of Expertise by the end of 2013 and also very important, make sure that proper infrastructures is available for people suffering from rare diseases and their families.

We hope that in the near future, there will be more legislation regarding orphan medicines in order to stimulate research and development of medicinal products for rare diseases by providing incentives to the pharmaceutical industry. This initiative will help to give patients suffering from rare diseases access to the same quality of treatment as other patients.

September 2009

### **New legal framework for non-interventional studies under discussion in France**

Paule Drouault-Gardrat, PDG Avocats, Paris

A Bill of Law entitled « Recherches sur la personne » (« Researches on person ») was filed with the French Parliament (« Assemblée Nationale ») on 6 January 2009. The French Parliament adopted the Bill on 22 January 2009.

The Bill of Law notably aims at harmonizing the regime of interventional and non-interventional clinical trials. Currently, non-interventional studies are not considered as clinical trials and are not regulated by the provisions of the French Public Health Code on clinical trials.

According to the Bill of Law, non-interventional studies will now require the information of the patients which can refuse to participate to a non-interventional study. Moreover, the sponsor will have to obtain the prior approval of the non-interventional clinical trial by the competent Ethic Committee. Finally, Good Clinical Practices for non-interventional clinical trials will be adopted.

Since 29 October 2009, the Bill of Law is now under discussion before the French Senate.

If the current provisions relating to non-interventional studies are adopted as such, it will be a significant change for sponsors of clinical trials in France.

### Pricing of medicinal products in Greece

Yannis Chryssospathis, M.&P. Bernitsas Law Offices, Athens

The system for the determination of the prices of medicinal products in Greece was modified by a relevant legal provision on the 7 August 2009.

More specifically, until now the price of a medicinal product in Greece was determined by the average of the two lowest prices of a drug in the 14 member states of the European Union and in Switzerland and its lowest price in the 10 member states that acceded to the EU in May, 2004.

Under the new regime, the determination of the price of a new medicinal product shall be derived from the average of the three lowest prices to a wholesaler of the medicinal product in the 26 member states of the EU.

The reason for such structural change taken by the Government is to limit the increase of the annual expenditures for medicinal products, which during the last five years is getting higher than the Community average.

The new regime has been already implemented with the price bulletin which was published on the 21 September 2009.

It is believed that with the new regime prices of medicinal products will be decreased and this will probably have as a consequence the increase of the parallel exports from Greece to other EU member States.

### HOSPITAL DEPT

During the last decade, the delays in the payments of the Public Hospitals for the medicinal products consumed by them were approximately 400-800 days.

In 1998, 2000 and 2004, the Greek Governments, by legislative regulations, paid the debts owing by the Hospitals to pharmaceutical companies, asking, however, from the latter discounts on the total amount due to each one of them and waiver from the interest due to them.

After 2004, despite the continuous reminders of the pharmaceutical industry, the Greek Government did not seem prepared to settle the continuously increasing debts to the pharmaceutical companies, that finally, in December, 2008, had reached the huge amount of Euro 2.8 billion.

In the beginning of 2009, following persistent efforts by the Greek Association of pharmaceutical Industries, the Greek Government understood that the issue of the debts should be solved. However, this time, the Greek Government, in its effort not to notify Brussels of the real amount of the debt, fearing more restrictive terms in the supervision of the Commission, proposed to the pharmaceutical industry the conclusion of a bond loan with the Postal Savings Bank under the guarantee of the Greek State, in order to settle only the 1/3 of the amount due to the pharmaceutical companies.

Despite the strong reactions of the pharmaceutical industry, the Greek Government sent in March, 2009, a draft tripartite agreement (Postal Savings Bank - Hospital - Pharmaceutical Company) by which all three parties would undertake to execute a Bond Loan, as well as a draft guarantee of the Greek State.

The terms of the tripartite agreement and those of the State guarantee were unacceptable to the pharmaceutical industry and for this reason no agreement has been reached until

now, despite the fact that countless draft agreements and drafts of the guarantee of the State have been exchanged between the interested parties.

It is expected that the new Government which was elected earlier this month will settle the problem.

### **Advertisement of medicinal products in Latvia**

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Recently the Government has adopted and submitted to the Parliament for final approval the draft amendments to the Pharmacy Law (1997). The draft law inter alia provides facilitating the dissemination of pharmaceutical advertisements in Latvia.

#### **Regulatory framework**

Advertising of medicinal products is regulated by the mentioned Pharmacy Law and Governmental Regulations No.167 (2007). In addition, the general provisions of the Advertisement Law and the Consumer Protection Law must be applied. The mentioned laws and by-laws transpose the respective provisions of the directive 2001/83/EC of the European Parliament and of the Council.

According to the mentioned Regulations No.167 the pharmaceutical NGOs may develop a joint code of ethics for the advertising of medicinal products that conforms to the mentioned laws as well as international ethical norms for the advertising of medicinal products. Therefore the market practices are conducted also by the Latvian Code of Practice of Advertising of Medicines (legally non-binding). In addition, the members of the Latvian pharmaceutical professional organizations follow the codes of ethics regarding promotion of prescription-only medicines adopted by the EFPIA and the AFA.

#### **Planned amendments- no prior approval of advertisement will be required**

Currently according to the Pharmacy Law an advertiser prior to dissemination of an advertisement must submit the advertisement materials to the State Agency of Medicines which must assess and approve their compliance to laws. Now it was established that the pharmaceutical NGOs have elaborated a sufficiently effective self-governing framework for advertising market practices (including the codes of ethics). Therefore it is planned that the prior approval of an advertisement before the State Agency of Medicines will not be required anymore. The Health Inspection may still provide surveillance on the content and form of advertising, but only in the scope of general market control (making inspections upon complaints from third parties or on its own initiative). Thus both state budget funding and the expenses of manufacturers and distributors will be saved.

#### **The main principles applying to advertising aimed at health-care professionals**

Advertising of medicinal products intended for specialists must include at least the following information:

- the most essential information of the product characteristics summary;
- whether the product belongs to the group of prescription or non-prescription products;
- the date of the last approval of the advertisement by the State Agency of Medicines (until the above amendments will enter into force).

The respective information must be (i) accurate, up-to-date, verifiable and complete so that the recipient may judge regarding the therapeutic value of the relevant product, and (ii) quoted precisely from medical journals or other scientific publications with references to the source of quotations, tables and other illustrative material. Advertisement may only indicate the name of the product if the advertising is intended as a reminder of the previously disseminated advertisement.

Advertisement may be placed only in scientific and informative press publications for specialists or in specially prepared advertising materials, which might not be distributed to the rest of the public.

### **The main principles applying to advertisement aimed at the general public**

It is prohibited to advertise to the general public following medicinal products (except vaccines): prescription products, products containing psychotropic or narcotic substances or the analogues thereof; and products, whose purchase price is partly or fully covered from the State budget resources. The manufacturers are not entitled to distribute medicinal products to the general public for promotional purposes.

The advertising must be designed in such a way that there could be no doubt that the information distributed is an advertisement and the product being advertised is a medicinal product.

If the products prohibited to advertise to the general public, are advertised on the Internet, the advertiser or disseminator of advertising must ensure the accessibility of the information only to specialists.

The advertising must include at least the following information:

- the name of the medicinal product, as well as the common name specified in laws regarding the labelling of medicinal products and the requirements to be met for the instructions for use of medicinal products, if the medicinal product contains only one active substance;
- information required for the correct use of the medicinal product;
- a clear and legible invitation to carefully read the instructions for use or the relevant information on the packaging;
- an invitation to consult with a physician or pharmacist regarding the use of the medicinal product; and
- the warning "*unreasonable use of medicinal products is harmful to health*". This warning must occupy not less than 10 percent of visual advertising. Font size should be such as to occupy most of the inscription technically possible part of the text of the warning area.

Among other, it is also prohibited to include an offer of medical treatment using mail services or providing advice in another similar manner and giving the impression that for determining a diagnosis a physician's consultation is not necessary.

It is prohibited to advertise (both to professionals and general public) the products not authorized in Latvia or lacking a valid marketing authorization or not authorized according to the centralized authorization procedure of the European Medicines Agency. In addition the advertising of medicinal products offered as a gift or compensation for the purchase of any goods or receipt of a service or where a gift is offered for the purchase of medicinal products (including an offer associated with the purchase of medicinal products to purchase medicinal products, other goods or services with a discount) is prohibited.

### **The main principles applying to the collaboration of the pharmaceutical industry with health-care professionals**

The advertiser or disseminator of advertising of a medicinal product may not supply, offer or promise any material or other kind of benefit regarding the prescription or distribution of medicinal products, except for the cases where it is to be used in the practice of medicine or pharmacy and its material value is insignificant.

The mentioned Regulations No.167 determines that the representation (entertainment) expenses in events with professional and scientific orientation shall be subordinated to the main purpose of the event, and they may be applied only to specialists. The health care specialists are not entitled to solicit, request or accept any material or other kind of the above prohibited benefits.

The free samples of products may be distributed by medical sales representatives only to persons having the right to prescribe medicinal products.

### **Committed infringements**

The most common infringements of the advertising rules relate to non-compliance of the contents of the advertisement with above mandatory rules or code of ethics. Also there were several instances of advertising the prescription medicinal products through internet, which is prohibited in Latvia. Regarding collaboration rules the most common violations relate to the illegal sponsoring of the physicians and to the organization of activities to the physicians with un-proportional allotment (according to Code of Ethics) between the scientific and recreational (entertainment) parts.

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### **Recent developments in drug patent law in Turkey**

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In 1995 Turkey has passed Laws on the protection of Copyrights, Patents, industrial designs and Trademarks as part of the process of implementation of the EU '*acquis communautaire*'. Law No. 551 on the Protection of Patents<sup>1</sup> is since January 1999 also applicable to pharmaceutical and veterinary products and to their process of preparation and production<sup>2</sup>. Since that time, enforcement efforts including considerable seizures of counterfeit material have increased; however, also some setbacks can be reported. Some provisions of the Turkish Ministry of Health's regulation issued in January 2005 on protection of undisclosed test data against unfair commercial use seem to undermine rather than to increase the protection for confidential data. Data protection is 6 years, limited to original products licensed in Member States of the European Customs Union first after January 1, 2001, for which no generic manufacturers had applied for licenses in Turkey as of January 1, 2005. Applications for admission of generic pharmaceuticals to the market were pending before the Turkish Patent Institute for a period longer than two years, creating vagueness as to what the protection status of confidential test and other data is.

Furthermore, in July 2008 the Constitutional Court ruled against the *criminal sanction provisions* of the Laws on the Protection of Patents and Industrial Designs and in effect barred the application of criminal sanctions for the infringements of these laws, though administrative fines and punishments like the closing down of a business and a disbarment from commercial activities for a period of one year may still be applied to these cases as the enforcement of the decision, cancelling the provisions that regulate the punishments in case of an infringement of the Laws, is delayed until one year after the decision being published in the Official Gazette on 10 June 2009. Since the ruling of the Constitutional Court, the Turkish Government has been in the process of preparing draft laws that should amend the various IP laws. The draft law will create a new legal basis for the sanctions applying to infringements of the Patent Law and will provide for imprisonment as well as for financial penalties. The draft law, sent to the Prime Minister in April 2009, is still pending; if it is not adopted before 10 June 2010, the courts will not be able to apply any sanction to persons that have infringed the Patent Law.

The upshot of these developments is that, depending on whether the new Law will be adopted before June 2010, patents on pharmaceutical products and on the process of their preparation and production will still be protected by sanctions, but these sanctions will be less severe. It is therefore expected that in the near future Turkey will encounter an increase of the production of generic pharmaceuticals. This will also augment the need of pharmaceutical companies, both the companies dealing with generic and those dealing with patent protected pharmaceuticals, of competent and expert legal assistance.

<sup>1</sup> Law No. 551 regulating the protection of patent rights, in force as of 27 June 1995, as amended by Law No. 556 of September 1995 and Law No. 4128 of November 1995.

<sup>2</sup> Transitional Article 4 of Law No. 551.

### **Our Members:**

For complete profiles of our members, please visit our website at [www.conference-bleue.com](http://www.conference-bleue.com) or contact:

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