



European Union of Medical Specialists
Union Européenne des Médecins Spécialistes

The Newsletter of European Medical Specialists

The European Medicines Agency (EMeA)



Towards closer collaboration with EU health professionals

Editorial

This issue of the Newsletter of European Medical Specialists presents a particular focus on recent developments in the field of medicines at the European level.

Even though we concede that this field is not the main area of activity for the UEMS, it is still of great interest to medical specialists. This is why we have decided to promulgate some recent and worthy pieces of information on pharmaceuticals.



Dr. Bernard Maillet
Secretary-General

tional partners, reinforcing the EU contribution to global harmonisation.

The EMeA began its activities in 1995, when the European system for authorising medicinal products was introduced, providing for a centralised and mutual recognition procedure for the pharmaceuticals' marketing authorisations. A single evaluation is carried out through the relevant Committee for Medicinal Products for Human (CHMP) or Veterinary Use (CVMP). The Committee's scientific opinion is then transmitted to the Commission which issues the authorisation in accordance with the EMeA's opinion. Two other Committees were also set up in 2001 and 2004 to look into applications for orphan drugs (Committee on Orphan Medicinal Products – COMP) and traditional herbal medicines (Committee on Herbal Medicinal Products – HMPC). On the occasion of a seminar organised on 28th March last in London, the EMeA invited attendance

of representatives of healthcare professionals associations with a view to increase both its visibility and to invite experts to contribute their knowledge in the field of medicines and diseases in Europe. Beside the network of 3,500 experts already constituted, the EMeA is looking for further support from health professionals themselves to underpin the work of the existing scientific committees.

This workshop was also an occasion for health professionals, and particularly doctors, to advocate a far greater involvement in the EMeA activities and a closer collaboration, notably in terms of exchange of information. At the seminar, **Dr. Bernard Maillet**, Secretary-General of UEMS, offered the UEMS expert-knowledge and information channels to assist the EMeA in this respect.

For further information on this issue, please contact the Secretariat of UEMS or consult the EMeA website: www.emea.eu.int.

Summary:

Special report

- European Commission warning against counterfeit medicines sold on the Internet
- First biosimilar drug authorised on EU market
- Generics likely to reduce healthcare costs, university study claims
- Early authorisation for emergency medicines
- **The Buda Castle in Budapest**
- **Important events & Publications**

The European Medicines Agency (EMeA) was founded in 1995 as a decentralised body of the EU. The EMeA responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use. For this purpose, it coordinates the evaluation and supervision of medicinal products throughout the EU by bringing together the scientific resources of the 25 EU Member States in a network of 42 national competent authorities. It also cooperates closely with interna-

Counterfeit medicines sold on the Internet

The European Commission recently warned consumers against an illegal obesity drug currently sold on the internet which has not passed the safety evaluation process of the European Medicines Agency (EMA).

According to the Commission, counterfeiting represents in general around 5-7% of world trade. This

phenomenon is deemed to create tax losses for Member States, represents a loss of income for companies and damages their own as well as their products' image. It is also likely to be responsible for job losses and, particularly in the pharmaceuticals sector, put consumer safety at risk.

A recent survey identi-

fied 170 medicines found in counterfeit distribution channels, mainly on the internet, over the period 2000-2005. The most 'popular' illicit drugs identified included lifestyle drugs, growth hormones for bodybuilding use and sleeping pills. Illegal copies of licensed medicines such as Viagra or Tamiflu have also been sold.



Source: www.telemmed.co.za

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First biosimilar drug on EU market

Two decades after the first drugs, produced by biotechnological means (as opposed to "normal" chemical pharmaceuticals), arrived on the EU market, a number of these patents are expiring. This means that the first 'biogenerics', also called biosimilar medicines, are about to enter the EU pharmaceutical market.

The European Commission supports this development, given that biosimilar alternatives are less costly to the purchaser while considered to be as safe and efficient as the "original" biotech drugs. The Commission has now granted the first marketing authorisation for such a biosimilar product. The medicament in question, Omnitrope, is intended for the treatment

of growth disturbance and growth hormone deficiency in children and adults. It had been evaluated and given a positive scientific opinion by the European Medicines Agency in January 2006. Omnitrope has been shown by studies to demonstrate comparable quality, safety and efficacy to a reference medicinal product already authorised in the EU, named Genotropin.

Additional information on the marketing authorisation for Omnitrope can be found at:

<http://pharmacos.eudra.org/F2/register/register.htm>.

Additional information on the EMA scientific guidelines regarding biosimilars can be found at:

<http://www.emea.eu.int/htms/human/biosimilar/biosimilarfin.htm>.

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Generics likely to reduce healthcare costs, University study says

According to a recent study of public generic medicines policy conducted by the Catholic University of Leuven (Belgium), encouraging the generics market could reduce the costs for EU health services.

Researchers from the Catholic University of Leuven (Belgium) examined the generic medicines policy in 11 EU Member States. They particularly focussed on pricing and reimbursement systems and incentives for doctors to prescribe, for pharmacists to

administer, and patients to use and demand generics.

The report claimed that if, for example, only the ten most prescribed drugs were replaced by generic equivalents, this would reduce public expenditure on pharmaceuticals by



Source: www.rx4u.com

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Early authorisation for emergency medicines

The European Commission recently decided to speed up the authorisation process of newly developed drugs for life-threatening diseases but under strict conditions. This decision aims to ensure that new treatments reach patients faster.

Under current rules, it takes around 10 years from the discovery of a new medicine until its introduction onto the market. This is naturally too long in the case of life-threatening diseases. New medicines can also be needed at short notice in case of emergencies like bioterrorist attacks or an influenza pandemic. This new set of rules will maintain high safety standards while allowing patients with unmet medical needs to receive new treatments earlier during product development. The new rules will allow medicines to enter the EU market using the "Conditional Marketing Authorisation" which will be valid for one year and which legally binds com-

panies to complete studies and confirm the medicine's safety and effectiveness.

These new 'conditional marketing authorisations' will only be granted if, in the judgement of the expert committee which advises the Commission on medicines, the benefits of the medicine outweigh its risks. Furthermore, that the benefits to public health of the immediate availability of the medicine outweigh the risk inherent in the fact that additional data are still required.

Medicines eligible for Conditional Marketing Authorisations are medicines for seriously debilitating diseases or life-threatening diseases, medicines for use in emergency situations as well as medicines for rare diseases (so-called orphan medicines). Under careful controls public health protection will be maintained by ensuring that further studies are completed, submitted, assessed and acted upon, to confirm the medi-

cine's favourable benefit risk profile. The regulators will also ensure that the medicine is very closely scrutinised once on the market.

This regulation will also stimulate innovation in pharmaceuticals by allowing return on investment earlier during product development and before the total cost of product development has been expended. This reduces the upfront costs of product development and by allowing earlier return on investment, reduces the costs of capital and hence total development costs.

The Commission has been working intensively with the Member States, the European Medicines Agency (EMEA) and the World Health Organisation to ensure preparedness for any possible future influenza pandemic. Conditional marketing authorisations will add an additional tool to the measures in place to authorise medicines, including vaccines, rapidly in the event of an influenza pandemic.

Our initiative can make a real difference for patients suffering from life threatening diseases for which no treatment exists. The new authorisation procedure can only be used under strict conditions so that safety is not endangered.



Günter Verheugen

European Commissioner in charge of Enterprise and Industry Policy

Conditional marketing authorisations will add an additional tool to the measures in place to authorise medicines, including vaccines rapidly in the event of an influenza pandemic.

On the regulation of medicines in the EU in general and specifically to access the regulation on Conditional Marketing Authorisations:

<http://pharmacos.eudra.org/F2/home.html>

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27-48% in many countries. It therefore called on the creation of a coherent EU generic medicines policy to boost development of a competitive European generics industry, which is said to be currently hindered

by delays in national pricing and reimbursement approvals.

The specific policy recommendations for the EU to strengthen its generic medicines markets, endorsed in the analysis, include free pricing policy encouraging price competition, information

on price differences to doctors and patients, boosting confidence in generic drugs and incentives both for doctors to prescribe and patients to ask for them.

The Report in question is available at:

<http://www.egagenerics.com/doc/simoens-report-2006-04.pdf>



Source: www.gov.im

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Budapest sightseeing - The Buda Castle

In view of the next meeting of the UEMS Council in Budapest, we provide in this issue further historical information on another famous monument: the Buda Castle.

“Romantic houses, mediterranean atmosphere and chattering cobblestone welcome tourists in the most famous district of Budapest. The Castle district which is colorful and quite rich in monuments promises visitors fascinating scenery and an unforgettable walk. It is good to know that cars can only park for a short time and pay the highest parking-fee in the city. It is recommended to take the Castle Bus (Várbusz) which departs from Moszkva Tér or the Funicular Railway, which offers a beautiful panoramic view, from Clark Adam Tér.



“The losses suffered under the Tartar Invasion of Hungary in 1241-42 that swept through the country and created mass devastation, proved that the flat land of Pest is indefensible against any attackers. Thus, in 1243 King Béla IV ordered that a royal castle be built on the other side of the Danube (on Pest Újhegy). The construction was finished by 1255 and the

accuracy of the design of this castle settled on a hill, was proved by it warding off future attacks. Anjou rulers started to build a palace in the 2nd quarter of the 14th century and in 1354 King Lajos I moved here with his royal court from Visegrád. The Turks plundered the castle in a mere two weeks in 1526.

www.budapest4you.hu

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If you have any views with regard to the issues covered in this Newsletter, do not hesitate to contact the Secretariat of UEMS.

Events

Tromsø Telemedicine and eHealth Conference

Tromsø (Norway), 12-14 June 2006

For further information: www.telemed.no/.

Global Alliance for Medical Education - 11th Annual Meeting

Rome (Italy), 18-20 June 2006

This Conference will aim to improve the perspective on international CME/CPD and achieve better understanding of the link between continuing quality improvement and CME.

For further information: www.game-cme.org.

ICT for Bio-Medical Sciences

Brussels (Belgium), 29-30 June 2006

For further information: ehealth@cec.eu.int.

Publications

Declaration of the International Alliance of Patients' Organisations on Patient-Centered Healthcare

www.patientsorganizations.org

European Standards on Confidentiality and Privacy in Healthcare

www.eurosocap.org