

EU: COMMISSIONERS LIIKANEN AND BYRNE RECEIVE EGA AWARD

The EGA Award 2004 has been granted jointly to Commissioners Erkki Liikanen and David Byrne for establishing and supporting the G10 High Level Group on Medicines. In the opinion of the EGA, "the G10 has fostered unparalleled dialogue between interested parties in the EU pharmaceutical health sector, established a solid foundation of priority policies for both the EU originator and generic medicines industry, and created an important model for policy discussion for future EU initiatives."

EGA Press Release
www.egagenerics.com/pr-2004-11-18.htm

FRANCE: SAVINGS MOUNT UP AS GOVERNMENT PROMOTES GENERICS

French government plans to promote the use of low-cost generic medicines are expected to save French patients and the healthcare system some € 330 million in 2005.

Generics Bulletin – www.generics-bulletin.com

AUSTRIA: MOVES TO INCREASE BENEFITS FROM GENERICS

In an effort to double the use of cost saving generic medicines to around 20% of all prescriptions, Austria's health minister, Maria Rauch-Kallat, has announced plans to charge patients lower co-payments for generics than for branded medicines. The measure is expected to generate € 35.8 million in savings for patients and health insurance funds.

Generics Bulletin – www.generics-bulletin.com

NETHERLANDS: HEALTH MINISTER PRAISES ROLE OF GENERICS



"... all European countries are seeking ways in which to do things more cost-effectively. You, the manufacturers of generic drugs, are our allies in this quest. It is therefore very important that you play your part, and that you

fulfil your role as effectively as possible. This will only be possible if certain other parties in the field cooperate... The Dutch government is now hard at work in revising the legislation which stands in the way of free competition on the generic drugs market."

J.F. Hoogervorst, Minister of Health, Welfare and Sport for the Netherlands, opening address - 10th Annual EGA Conference in Amsterdam - 8 November 2004

EGA Home Page – www.egagenerics.com

PORTUGAL: "THE RESULTS ARE EVIDENT."

"In the current social context of increased life expectancy and an aging population, the Medicines Policy adopted has helped to provide people, especially the more vulnerable and underprivileged, with an alternative in the use of medicines that never existed before."

Luís Filipe Pereira, Minister of Health Care for Portugal
www.egagenerics.com/ega-events.htm

GERMANY: EVEN MORE SAVINGS FROM GENERICS

The German Ministry of Health expects to save another € 2 billion each year through new measures to stimulate the use of generic medicines in addition to the € 3.4 billion in annual savings already generated by generics.

Generics Bulletin – www.egagenerics-bulletin.com

Generics and Sustainable Healthcare

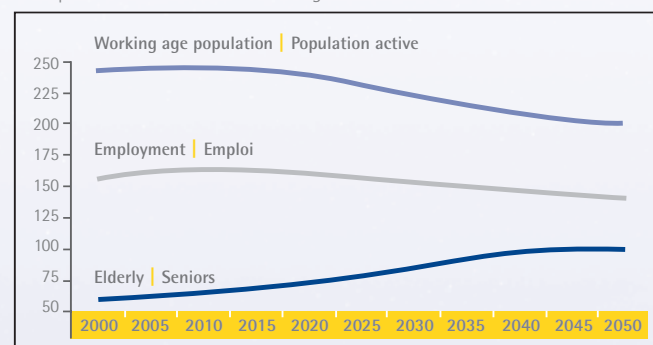
AGEING POPULATIONS MEAN RISING HEALTHCARE COSTS

As Europe's population grows older and healthcare demands increase, Europe faces an alarming scenario of rapidly increasing healthcare costs.

According to studies from the EU's Economic Policy Committee on the "Budgetary challenges posed by ageing populations", the number of elderly citizens in the European Union is rising dramatically while the number of working age citizens contributing to social service funds is rapidly falling. By 2050 it is estimated that each elderly person in the EU will be supported by only two working age citizens instead of by four, as is currently the case.

Active and inactive persons in Europe (millions)
An Ageing Population: How to sustain affordable medicinal care?

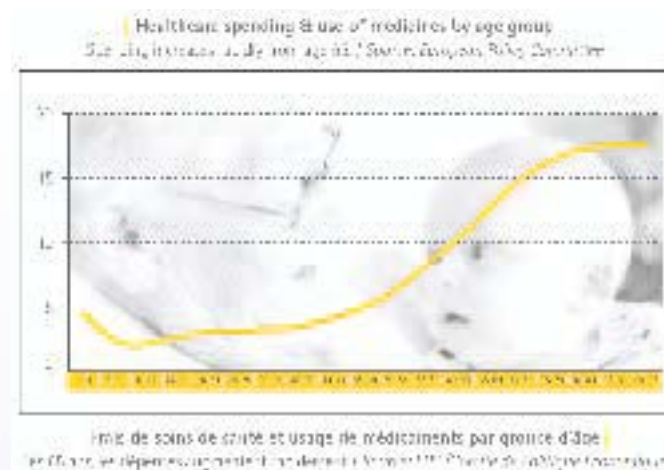
Population active et inactive en Europe (millions)
Population vieillissante : Comment garantir des soins de santé abordables ?



- Working age population refers to persons aged 15 to 64
 - Elderly population refers to persons aged 65 and above. Source: EPC
 - La population active correspond à la tranche d'âge de 15 à 64
 - Les seniors correspondent à la tranche d'âge de 65 ans et plus
- Source : EPC (Comité de Politique Économique)

"HOW DO WE PAY FOR THE YOUNG AND THE ELDERLY?"

In addition, citizens aged 65 and over account for 30% to 40% of healthcare spending – far more than any other pop-



ulation group. According to the EPC report, the situation is roughly similar right across Europe: "... expenditures per person increase with age, and are particularly high for the oldest age groups ...". The report continues to warn EU policy-makers that public spending on healthcare will rise by 4% to 8% of GDP over the next few decades, and insists "...that the budgetary impact of ageing is substantial, making it more difficult for Member States to comply with the budgetary requirements of EMU (Economic and Monetary Union)."

GENERICS OFFER A SOLUTION

One readily available solution to these problems can be found, in part, by increasing the use of generic medicines. These competitively priced therapeutic equivalents to patent expired originator pharmaceuticals have demonstrated they possess the same quality, safety, and efficacy as their originator products as they go through the same regulatory procedures.

Taking these facts into account, decision makers across Europe should consider adopting further measures to facilitate and encourage a wider use and acceptance of generic medicines by doctors, pharmacists and patients •

¹ Economic Policy Committee (EPC), "Budgetary challenges posed by ageing populations: the impact on public spending on pensions, health and long-term care for the elderly and possible indicators of the long-term sustainability of public finances", Brussels, 24 October 2001 (EPC/ECFIN/630-EN final). Available on-line at: http://europa.eu.int/comm/economy_finance/epc/documents/summary_en.pdf

ACCESS TO MEDICINES

EU Responds to WTO Agreement on Access to Medicines

On 30 August 2003 the WTO adopted a Decision defining the authorising of compulsory licensing of patented pharmaceuticals as one strategy to help confront the growing crisis of access to essential medicines in the developing world.

The European Commission's recently proposed "Regulation on compulsory licensing of patents for export of pharmaceutical products to certain countries with public health problems" is designed to create the legal framework to implement the WTO Decision into EU Member State law.

The proposed EU Regulation specifies that a compulsory license can only be issued by a least developed country or a country with no manufacturing capacity. The compulsory licence imposes clear conditions upon the licensee defining which medicines are to be manufactured, and in what amounts, while requiring a fee to be paid to the originator company and/or patent holder. The products manufactured can only be sold in the country for which the licence was granted and safeguards are provided against re-importation into the EU. Similarly, it

will be important to ensure that undue bureaucratic red-tape will not hinder companies from participating in the compulsory licensing system. The Commission's proposal must be examined very closely in this regard.

Moreover, once the new legal framework is in place in the EU, it will be necessary to establish the practical issues involved in meeting the medicinal requirements of developing countries. These are often countries with severely limited ability to pay for even the lowest cost medicines available and must rely on assistance from the world's richer nations. European companies making "generic" formulations of patented medicines for designated needs will have to invest heavily to develop and manufacture them, and will not be able to rely on sales to recoup these costs on European or US markets where the patent holder retains market exclusivity on the product. In this context it will be important to see what incentives or guaranteed purchase funding can be provided to help companies provide these specially designated medicines •