

### BELGIUM: GENERIC MEDICINES CAN BRING SUBSTANTIAL SAVINGS OF UP TO 55%!

The Belgian consumer organisation Test-Achats has calculated that senior citizens and families with children can save up to 55% on their pharmaceuticals bill by buying low-cost generics. Test-Achats encourages increased use of generics which currently account for only 7% by volume of all medicines used in Belgium. (*Test-Santé* n°61, juin 2004)

### FRANCE MOVES FAST TO END ABUSE AGAINST GENERICS

The French government is determined to end the widespread practice in France of extending market exclusivity by as much as 10 years through minor variations to the original drug. To this end, France is hurrying to implement the new laws on data exclusivity from the EU's revised pharmaceuticals legislation.

### GENERIC MEDICINES REDUCE SPANISH PHARMACEUTICAL SPENDING

Initiatives to promote generic medicines are proving effective in reducing the pharmaceutical spending in Spain. According to data recently released by the Spanish ministry of health, during the period July 2003 to June 2004 spending on pharmaceuticals rose only 10.14% compared to 12% the previous year. The measures used include increased generic prescribing and obligatory generic dispensing at the pharmacy.

### GENERICS CAMPAIGN IN POLAND HELPS PATIENTS RECEIVE MEDICINES

Approximately 25% of patients in Poland leave the pharmacy without their medicines – either because they can't afford their prescription or because they don't know that their prescriptions can be substituted for lower-priced generics.

To help ensure the patients can afford their prescriptions, a campaign to promote the awareness of generic medicines was recently run in Poland by POLFARMED, the Polish generic industry association and the Polish Pharmaceutical Chamber of pharmacists. The campaign was carried out in the ten major Polish cities under the title "Pharmacists to Patients". It provided information on what a generic medicine is, its availability and a patient's right to substitution.

### GENERIC COMPETITION SAVES DENMARK MORE THAN €120 MILLION IN 2004

A recent study shows that the price of 23 medicines were lowered during 2001-2003 due to generic competition. The reduced prices on these products alone will save Danes more than €120 million in 2004.

### DUTCH HEALTH MINISTER TO DELIVER KEYNOTE SPEECH AT EGA CONFERENCE 2004

The 10th Annual EGA Conference will be organised in the Netherlands to coincide with the Dutch Presidency of the European Union. J.F. Hoogervorst, Minister of Health Care for the Netherlands will deliver the keynote speech on the topic "The importance of Generic medicines in European healthcare: Dutch Policy and G10 initiatives."

## COMPETITION

# A Lisbon Strategy for Pharmaceuticals: Research Funds and Generic Competition



Jose Manuel Barroso | Président European Commission

José Manuel Barroso has pledged his tenure as President of the European Commission to meeting the Lisbon targets of making the EU "the most competitive and dynamic knowledge-driven economy by 2010". In fact, his Commission is already being called the "Lisbon Commission". For this pledge to benefit the pharmaceutical industry, Europe must dramatically increase the resources it commits to basic medical research while improving competition within the sector. Europe, once the world's leader in the production of new medicinal treatments, has fallen far behind the US in the number of new chemical entities patented each year. For Europe to regain its leading position in the world, Rory O'Riordan, president of EGA, has called for the creation of an EU equivalent to the United States' National Institutes of Health (NIH) to ensure adequate funding for European phar-

maceutical research. The NIH, a well-coordinated grouping of major research institutions throughout the United States, is directly funded by the US government to the amount of \$25-27 billion annually. In the EU, current proposals will only increase research funding for pharmaceuticals to €2 billion. In addition, the penetration of generic medicines in most EU countries remains very low, lagging far behind the 50% figure achieved in the US. Consequently, Member States must rapidly introduce the measures recommended by the G10 High Level Group on Pharma to strengthen market competition from cost-effective generic medicines. The G10 measures include increased generic prescribing and dispensing, as well as strengthening consumer awareness of the benefits of generic medicines. The competition from cost-effective generic products stimulates the drive to discover new medicinal treatments. The savings from lower-priced generic medicines frees up healthcare funds to make government reimbursement of the originator industry's newer products easier for budget conscious health ministers. In short, EU generics and originator pharmaceutical companies must work in an environment of healthy competition to improve patient access to effective and affordable medicines •

*"The competitive future of both sides of the European pharmaceutical industry is inextricably linked to each other's continued viability on the world market. The challenge now is to increase the synergies between generic medicines and originator pharmaceuticals so as to enhance competition and to improve the availability of effective and affordable medicinal treatment to patients throughout the EU."*

Rory O'Riordan | President EGA

## INDUSTRY

# EU Overtakes US on Developing Biogenerics

### THE ADVENT OF BIOTECH PHARMACEUTICALS

Over the last 20 years recombinant DNA (r-DNA) technology has produced safe and effective therapeutic proteins, providing important new medicinal treatments derived from biotechnology to meet Europe's healthcare needs. But these new "miracle treatments" are costly. To increase patients' access to these expensive medicines, competition from more affordable comparable products must be introduced after a reasonable period of market exclusivity for the originator product.

### LEGAL FRAMEWORK FOR BIOGENERICS

Until very recently, however, no legal framework has existed in any regulated market to recognise generic medicines derived from biotechnology. Competition from cost-effective conventional generic medi-

cines is encouraged by providing an abridged registration procedure. The manufacturer of a generic medicine must prove the quality of its product. It must also demonstrate the generic medicine's therapeutic equivalence with the well-known originator product through bioequivalence studies.

This year the EU established its competitive advantage in the biogeneric sector over countries like Japan and the United States by adopting provisions in the review of EU pharmaceutical legislation. This established a legal base for biogenerics, recognising them officially as "similar biological medicinal products".

Biosimilar applications will be processed through the European Medicines Agency (EMA). The extent of clinical trials required will be based on the complexity of the product in question.

### PRACTICAL CONCLUSIONS

So when will lower-priced biogenerics become available to European patients and healthcare systems? Hopefully soon, as some leading generic companies are now gearing up to produce biosimilar products.

In the meantime, efforts are being taken to introduce legislation allowing for the production of biogeneric products in the United States. To maintain its competitive advantage, Europe must act quickly to implement fully its new laws on biogeneric medicines. Doing so will stimulate the creation of new research jobs. It will boost Europe's trade balance in pharmaceuticals. But more importantly, it will deliver advanced medicinal treatment to its patients at affordable prices •

BIOTECH MEDICINAL PRODUCTS SOON TO COME OFF PATENT

INDICATION	PRODUCT	EU PATENT EXPIRY
Renal anemia	EPO	2005
Diabetes	Insulin	2005
Neutropenia	G-CSF	2006
Growth deficiency	HGH	2002
Multiple sclerosis	Beta-interferon	2003
Hepatitis C	Alpha-interferon	2002