



Making Medicines Affordable

# Conference

→ HIGHLIGHTS

## 16<sup>th</sup> EGA ANNUAL CONFERENCE

### Generic Medicines: Enhancing Pharmaceutical Competition and Ensuring Healthcare Sustainability



Didier Barret

*"Increasing generic medicines market penetration is the fastest way towards considerable and sustainable savings for healthcare systems in Europe". This was the message delivered by EGA President Didier Barret at the European Generic medicines Association's Annual General Meeting in Rome on 3 and 4 June 2010.*

Barret stressed that sustaining the industry must be based on 3 pillars: fair access to market; fair pricing; and fair competition. *"This will lead to the sustainability of healthcare systems by increasing patient accessibility through the affordability and availability of medicines, whilst promoting quality, fostering innovation and helping Member States to balance healthcare budgets,"* he said.

**Giorgio Foresti**, President of Assogenerici, noted that the global financial crisis has led to cost cutting across the entire health sector. The problem in Italy is that authorities have put pressure on prices without promoting the use of cost-saving generic medicines, he maintained.

### SESSION 1 | HOW TO INCENTIVISE PATIENT ACCESS TO GENERIC MEDICINES AND ENSURE SUSTAINABILITY OF THE ITALIAN HEALTHCARE SYSTEM

Generic medicines should not be considered solely as a means to "mitigate" market prices and public pharmaceutical expenditure, said **Andrea Pezzoli**, from the Antitrust Section of the Italian Competition Authority. **Giorgio Foresti** of the National Association of generic medicines manufacturers (Assogenerici) added that if generic medicines were permitted to achieve the same level of penetration as in the rest of the EU, healthcare would benefit in the longer term.

However, despite the Italian Medicines Agency's claim that in 2010, newly marketed generic medicines could produce

savings of €150 million, the country's government's focus on short term results involving price cuts could put the generic medicines industry at "real risk". Italy's recently introduced Law Decree for economic recovery is both "myopic" and lacking *"any measure to promote the generic medicines market"*, said Foresti. However, some hope remains for the industry, as **Mario Alberto Nezza**, Head of Cabinet of the Ministry of Health, suggested that the legislation could be revisited.

Advocating a greater role for generic medicines in the panel discussion were **Guido Rasi**, Director General of AIFA, the Italian



#### The European Generic Medicines Industry Calls for a Sustainable Generic Medicines Market that Facilitates Higher Savings While Enhancing Dynamic Competition

The EGA therefore recommends:

- that the EU off-patent market be based on the principle of headroom for competition
- the removal of hurdles to the immediate entry of generic medicines on patent expiry
- the introduction of mechanisms to stimulate competition from generic medicines
- the creation of a sustainable pricing & reimbursement system for long-term competition, enabling short, mid- and long-term savings

Medicines Agency, **Cesare Corsi**, Head of the Italian Senate Commission on Industry, Trade and Tourism, **Paolo Ruta**, coordinator of the Round Table on Pharmaceuticals for the Ministry of Economic Development, **Loredano Giorni** and head of the pharmaceutical sector of the Tuscany Region and **Fulvio Moirano** Agenas Director, the Agency for regional health services •

## SESSION 2 | FUTURE POLICY ENVIRONMENT FOR THE EUROPEAN GENERIC MEDICINES INDUSTRY IN LIGHT OF THE EU PHARMACEUTICAL SECTOR INQUIRY

Abusive practices that prevent generic medicines from entering the market are jeopardising the stability of Member State health services. This was highlighted by the European Commission's Pharmaceutical Sector Inquiry, which also showed that there are "huge potential savings that are not being used", said **Giulia Del Brenna**, Head of Unit - DG Enterprise European Commission. **Jytte Lyngvig**, CEO of the Danish Medicines Agency agreed, maintaining that while much had been done to establish a competitive generic medicines market, there was still further to go to ensure sustainability. This could perhaps be achieved by placing more emphasis on efforts defining "how to facilitate public spending and help healthcare systems provide quality, safe and efficient medicines", suggested **Antonyia Parvanova**, ALDE MEP.

Whilst the Sector Inquiry might raise questions as to how to secure the future of the generic medicines market in Europe, it has at least served part of its purpose by encouraging the Commission to investigate abuse of dominance practices and anti-competitive agreements, noted **Monica Alfaro Murcia**, from DG Competition Pharmaceutical Task Force European Commission. Furthermore, future patent applications will be more closely scrutinised and proposals for a Community patent are under consideration, said **Dieter A Tzschoppe**, Director Pure and Applied Organic Chemistry – European Patent Office •



This Interactive panel discussion consisted of: Monica Alfaro Murcia – DG Competition Pharmaceuticals Task Force European Commission | Giulia Del Brenna, Head of Unit - DG Enterprise European Commission | Antonyia Parvanova, MEP for ALDE | Dieter A Tzschoppe, Director Pure and Applied Organic Chemistry – EPO | Jytte Lyngvig, Chief Executive Officer – Danish Medicines Agency | Greg Perry, Director General – EGA

## SESSION 3 | PANEL DISCUSSION ON NATIONAL MARKET DEVELOPMENTS AND THEIR IMPACT ON GENERIC MEDICINES COMPANIES

A lack of proper incentives from EU Member State authorities to prescribe, dispense or demand generic medicines is preventing their effective penetration of the pharmaceutical market. Directors of national generic medicines associations on the panel cited short-term

pricing pressures, including tendering and radical price and reimbursement cuts.

Although these are generally a common denominator amongst European generic medicines associations and companies, there was some encouraging feedback from the Director of the French national generic medicines association concerning efforts made by the health authorities to create a sustainable environment for higher savings, involving generic medicines. They include an agreed automatic generic medicines substitution rate of 80%, an increased number of generic medicines in the repertoire list and more incentives for physicians and patients to prescribe and ask for generic medicines.

"The solution to greater savings is to increase generic medicines volumes as opposed to cutting prices," suggested **Hugo Carradinha**, EGA Senior Manager Economics Affairs during his presentation •

**Greg Perry**, EGA Director General, stated that in order for the EU pharmaceutical Sector Inquiry to be a real success it must promote mechanisms that:

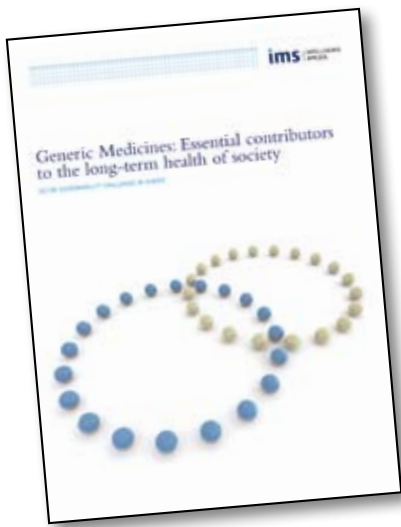
- Foster innovation
- Increase competition
- Improve patient access to affordable treatments
- Ensure healthcare sustainability

### Recommendations for the Uptake of Generic Medicines



OVERVIEW OF THE KEY DEVELOPMENTS IN EUROPEAN MARKETS AND CURRENT TRENDS  
Hugo Carradinha | EGA Senior Manager Health Economics Affairs | Rome, 03 June 2010

## SESSION 5 | THE DYNAMICS OF THE GROWING GENERIC MEDICINES MARKET: EUROPE AND BEYOND



"Generic medicines in the EU have generated savings in the order of €30 billion, excluding those made from the stimulation of competition with the pharmaceutical sector as a whole". This message was delivered by Alan Sheppard, Global Head Generic Medicines at IMS, citing the recently launched IMS report "Generic medicines: essential contributors to

the long-term health of society - sector sustainability challenges in Europe".

However, despite their obvious benefit to the healthcare economy, "generic medicines companies are in the midst of a period of great pressure from cost containment measures", Per Troein, Vice-President Strategic Alliances Europe, Middle East & Africa - IMS Health, conceded. But they are not alone in feeling the impact of the global economic downturn, with additional burdens also being placed on off-patent products and original products, as well as on wholesalers and pharmacies. At the same time, demographic lifestyle shifts and changing prescriber behaviour are responsible in some cases for the reduction in generic medicines volumes, Troein suggested.

Emphasising the need for "a strong, sustainable, profitable and safe generic industry in France and Europe", Noël Renaudin, President - Comité Economique des Produits de Santé (CEPS), noted that the generic medicines market was undergoing an evolution. He highlighted a growing number of diseases that are being treated solely with generic medicines and the fact that these medicines are now often considered as the best treatment available. Renaudin suggested that authorities have come to the

realisation that resources are limited because of the increasing cost of medicines. Other positive changes include the improvement of social financing and signs that the generic medicines industry is prepared to assume responsibilities traditionally fulfilled by the originator industry, such as pharmacovigilance. This contrasts with the negative development of some countries' use of stringent price decreasing mechanisms, he concluded.



Noël Renaudin

#### IMS REPORT HIGHLIGHTS IMPORTANCE OF GENERIC MEDICINES INDUSTRY SUSTAINABILITY FOR THE EU

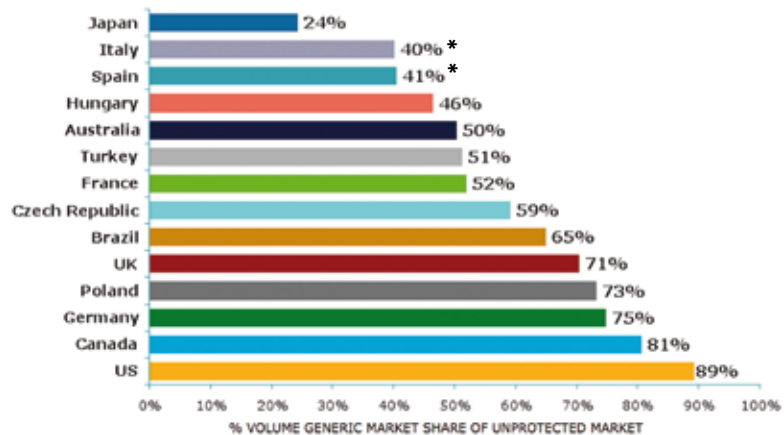
The key conclusions of the report are that generic medicines:

- Provide an affordable, gold standard medication for many major illnesses
- Allow access to medicines for a greater proportion of the population
- Stimulate healthy competition with the branded sector
- Deliver savings to national health bills
- Enable future long-term savings in the expanding role of medicines vs hospitalisation
- Are high quality products

The IMS report can be found at this address:

<http://www.imshealth.com/portal/site/imshealth/menuitem.0103f29c72c419cd88f611019418c22a/?vgnnextoid=1cc50db58e3f6110VgnVCM10000071812ca2RCRD>

Potential savings in many European countries are not fully exploited due to lower utilisation of generic medicines in key therapy areas post loss of exclusivity.



Source: IMS Health, MIDAS, Market Segmentation, MAT Jun 2009, Rx only

GENERIC MEDICINES: ESSENTIAL CONTRIBUTORS TO THE LONG TERM HEALTH OF SOCIETY  
SECTOR SUSTAINABILITY CHALLENGES IN EUROPE  
Alan Sheppard | IMS Global Head Generic Medicines | Rome, 04 June 2010

\* The values shown for Spain and Italy also include other out of patent products (e.g. copy products) and not just generic products. Based on local market definitions used by EGA national associations, both countries are closer to 12% generic medicines utilisation.

## SESSION 6 | CEO PANEL DISCUSSION LOOKING BEYOND THE WORLD ECONOMIC CRISIS MARKET TRENDS AND OPPORTUNITIES FOR THE EUROPEAN GENERIC MEDICINES INDUSTRY

Generic medicines are a key component of addressing rising healthcare costs, whilst maintaining quality of care. As such, their use should be further incentivised by Member State governments. The panel agreed that it is equally vital to encourage payers to value effectively the role of the manufacturer, pharmacist, physician and wholesaler within the market structure.

However, despite noting the severe pricing pressure on the industry, CEOs of the world's leading generic medicines companies expressed a positive outlook due to continued and promising increases of generic medicines volumes as well as the emergence of new products into the market.

The generic medicines industry has an undoubtedly bright future, but CEOs believe there is a need to:

- Achieve sustainable pricing, through addressing the problems of unsustainable lower prices that put the very survival of the industry at risk
- Constantly bring new products to market
- Enter new therapeutic fields, such as respiratory and biosimilars •



CEOs who contributed to the consensus findings included: Didier Barret, President Mylan EMEA & Mylan S.A.S. | Gudbjorg Edda Eggertsdottir, Deputy CEO – Actavis | Nick Haggart, Head Commercial Operations Western Europe – Sandoz | Rory O’Riordan, CEO – Clonmel Healthcare & Vice President – Stada Europe | Emile Loof, President & CEO – TEVA Pharmachemie. The panel was moderated by Andrew Jack, Pharmaceuticals Correspondent for the *Financial Times*. The conference was closed by Greg Perry, EGA Director General.

**GENERIC MEDICINES:**  
A tradition of quality, safety and efficacy



EUROPEAN GENERIC MEDICINES ASSOCIATION

**GENERIC MEDICINES:**  
Front-line treatments for chronic illnesses & conditions



EUROPEAN GENERIC MEDICINES ASSOCIATION

**GENERIC MEDICINES:**  
Ensuring equal access to healthcare provision



EUROPEAN GENERIC MEDICINES ASSOCIATION

**GENERIC MEDICINES:** Ensuring sustainability of healthcare systems throughout Europe



EUROPEAN GENERIC MEDICINES ASSOCIATION

**GENERIC MEDICINES:** Providing 150 000 direct jobs throughout Europe



EUROPEAN GENERIC MEDICINES ASSOCIATION

**GENERIC MEDICINES:** Leading in manufacturing pharmaceuticals in the EU



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The EGA is the official representative body of the European generic and biosimilar medicines industry, which is at the forefront of providing high-quality affordable medicines to millions of Europeans and stimulating competitiveness and innovation in the pharmaceutical sector.