



*Making Medicines Affordable*

## **Europe's Pricing & Reimbursement Systems: Help or hindrance for increasing competition in the EU?**

**E.G.W.H. Loof, President of EGA.  
Malta, 20 June 2005**

### **Summary of Presentation**

Market entry for pharmaceuticals in the EU is a three step process: 1. Marketing Authorisation; 2. Pricing; 3. Reimbursement. The MA procedures were recently re-examined during the EU Review 2001. However, the Pricing Directive, implicitly including reimbursement, dates back to 1989. Basically it only concerns the 'transparency' of pricing and maximum process times (2 x 90 days). In the late 80s, this Pricing Directive served obvious purposes. Although today's pricing in the EU-25 might seem complicated, it is uniformly regulated by Directive 89/105/EEC.

Reimbursement is an integral part of the social and healthcare system in each of the 25 Member States. These systems have evolved over the course of history. It was agreed by treaty (Rome 1957 and Amsterdam 1999) that the social system, and thus reimbursement, should be the exclusive domain and responsibility of the Member State.

Reimbursement of professional services (i.e. pharmacists & pharmaceuticals) is more complicated than pricing, and theoretically involves 8 models which are applied in a different mix in each country.

The reimbursement system involves a lot of 'competent authorities'. In most cases each of the Autonomous Regions, Landers, Provinces, etc, have their own. If someone were to count them, the tally would probably exceed 400 decision-making bodies or 'competent authorities' in the EU.

Reimbursement is a 'hot' topic today because it determines the outcome of the increasing financial burden of premiums for social welfare programmes and taxes. Together these costs are eventually borne by the citizenry of each nation.

Reimbursing generic pharmaceuticals is less costly by the very nature of generic products.

Our research shows that reimbursement process time varies from 2 to 36 weeks maximum and 2 weeks minimum. The total outcome is a "sub-optimisation" of every aspect, both for industry and for healthcare systems.

The big question is why a generic medicine cannot be reimbursed immediately in cases where the brand name drug has already been reimbursed. The generic medicinal product has been proven safe and effective for human use for at least 15 years. It is bioequivalent by definition and, by its very nature, will be less expensive for the healthcare system. Why not start fair competition as soon as possible?

The EU Member State healthcare systems and the generic medicines industry have a common interest here. Without a sound and healthy generic medicines industry in Europe, optimal costs for a healthcare system in the long run are not possible. With generics, 50% of the volume of medicines prescribed will cost only 15% to 20% of the total cost of pharmaceutical care.

**Help or hindrance?** We should like to conclude that at this moment the existing EU pricing and reimbursement systems and methods are definitely a hindrance to an optimal system of pharmaceutical care and therefore for optimal healthcare costs at the national level. National attention is not only mandatory, it is also a national responsibility. By taking a closer look at today's reimbursement systems, EGA members, national governments and 'competent authorities' can work together to create greater help.