



The market for herbal products in Germany was an international model for a very long time. The Commission E had developed the plant monographs, which were the basis for registrations and about half of the products sold in Germany were prescribed by physicians and reimbursed by the health insurance system. This system is now changing because of the government's new health regulations, which came into force January 1, 2004. Reimbursement of drugs is limited to prescrip-

# EU Market Changes: Challenges & Opportunities

Companies must understand the changing landscape for supplements and herbs in the EU.

By Joerg Gruenwald

Joerg Gruenwald, PhD, is president of Phytopharm Consulting, Institute for Phytopharmaceuticals, a consulting company for herbal medicines and dietary supplements, specialized in international alliances, product and partner findings for new product development and regulatory advice worldwide. He is also the author of the PDR for Herbal Medicines. Dr. Gruenwald can be reached at Waldseeweg 6, D-13467 Berlin, Germany; 49-30-4000-8100; Fax: 49-30-4000-8400; E-mail: jgruenwald@phytopharm.org; Website: [www.phytonet.com](http://www.phytonet.com).

tion only products, which means that very few herbal products will be reimbursed, as they were in the past. There will be a list of exceptions, however, they will only be available in the case of severe diseases for which a particular herbal products must be standard therapy. In addition, the doctor must request reimbursement for each individual case. At the moment, only St. John's Wort for mild to moderate depression is on this exception list, the manufacturers and associations continue to fight to get further herbal products included. The consequences for herbal products and the herbal industry are dramatic because patients usually receive another prescription for their diseases and illnesses and will end up getting a prescription for more the expensive synthetic products, which are generally characterized by higher rates of side effects and interactions.

The month of January revealed a startling 70% drop in the value of registered OTC drugs prescribed by doctors. This can be partially explained by early purchases in December 2003, because at that point in time reimbursement of OTCs and herbal products still existed, but it is

expected that the sales of herbal products will drop by approximately 25-35% in 2004 compared to 2003.

There have also been continuous increases in the regulatory requirements for herbal products. Specifically, a new guideline on drug interactions is under discussion, which will require manufacturers to at least perform *in vitro* assays. If these assays reveal any indication of a potential drug interaction, further *in vivo* data will be required. These regulations are very controversial, because it can be shown that many food items, such as honey, red wine or spices, also interact with the *in vitro* test system. The companies that have a long-term experience in direct OTC sales to consumers will profit, but many small and medium size companies, which were dependent upon doctors' prescriptions, will suffer the most.

Future hope for new products lies in the new traditional herbal medicines directive, which must be implemented into national EU laws to allow products, with at least 15 years of sales history within the EU, to be registered in the other European member states, without requiring additional data on safety and efficacy. It is still unclear, however, if herbal products will also be sold under the supplement directive.

Every change in market conditions offers chances and opportunities. Some regulatory categories such as "balanced diet" or "partial balanced diet" are more popular because combinations of vitamins, minerals and herbals can be applied for special disease conditions, such as diabetes or high cholesterol levels. These products are now being tested for new indications and their limits are being explored.

Insurance companies are coming up with new policies to cover natural therapies and herbal products but most consumers are still hesitant. Mergers and acquisition activity will increase due to decreasing company values and perspectives and the need for new money. It is expected that the market will consolidate further and consumers will accept the self-medication status of herbal products within one to two years. TW