

## Can Europe Become One?

by Katharine Gladstone



Over one and a half millennia ago, the Roman Empire ruled Europe. As we enter the next millennium, Europe is attempting to unite once more. Do Europeans believe that they will succeed where the Romans ultimately failed?

Thirty years ago, Europe was at the forefront of science, discovering 65% of the world's new medicines. In 1997, out of 47 new substances in the world, only 19 (40%) were discovered and developed in Europe. The European pharmaceutical industry has weakened and in order to remain competitive with the global market, European countries are combining their political and economic strength to form a single market. As the European Union (EU) began to integrate the European pharmaceutical industry, they uncovered a wealth of problems.

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The EU improved the drug approval process as a first step towards a single market. Previously, each EU country approved medicines according to their own set of regulations and specifications. Medicines were often reconfigured to meet requirements in another country. This was an extremely costly process as well as a barrier to the free circulation of medicines. The EU, therefore, created the European Medicines Evaluation Agency to evaluate drugs centrally. In addition, the mutual recognition approval process was introduced, which recognised that one country's regulations could offer equivalent levels of protection to that of the others.

Despite integral flaws in current approval processes, the EU have created a more unified market together with the means to bring products to the market more effectively. By 1997, trade in the European pharmaceutical industry was looking more promising. The EU produced ECU 87,000 million worth of products, that is 40% of global production. The trade balance (the balance of exports and imports) for the EU was ECU 15,000 million in Europe's favour. Two-thirds of this income was spent on research and development. However, Europe still has a long way to go to regain its competitive share of the global market.

Improving the drug approval process alone is not enough to create a single market. Big differences exist between the national markets, for example, in disease incidence, standard of living, demand for and consumption of pharmaceuticals, distribution costs, and

health care systems. Drug demand is further complicated by the interactions of the patient, the prescribing doctor and social security bodies.

All these factors summate to large variations in drug pricing across European countries. Each country controls drug prices either directly or indirectly by policies that affect prescription and demand. These price differences have created a parallel market. Traders can buy medicines in a 'low-cost' country to sell for profit in a 'high-cost' country. Ultimately, the patient and the health care systems suffer from the loss of profits.

At the end of 1998, the EU met to discuss their next move. "We realise that we have to consider whether the Single Market means having the same price, and if we were to have the same price what the price would be" Martin Bangemann, the EU Industry Commissioner, reported ("Speech by Martin Bangemann, Member of the European Commission at the Second Frankfurt Round Table on the Pharmaceutical Single Market" at [www.europe.eu.int](http://www.europe.eu.int)). He added that "having prices converge to the level at which they are in the lowest-price countries would mean that research would in future be undertaken outside Europe or not at all. Selling medicines throughout Europe at the higher level would mean potentially denying citizens of medicines".

Neither option, that is, to leave drug prices as they are or to force price convergence, was viable. The EU agreed that the aim of the single market is to give patients access to the medicines they need at affordable prices and to create incentives for innovation and industrial development. To achieve these aims, they are taking a 'middle way' approach. Drug companies and the public authorities of individual countries are being encouraged to negotiate reasonable prices and profit margins that also allow companies to sustain competitive research and development.

The EU have also grouped the market into three sectors: non-prescription, out-of-patent and in-patent drugs. They identified ways in which to stimulate competition in each of these areas. In 2000, the EU will review the licensing system for generic (out-of-patent) medicines, to encourage the use of generic products. They also plan to remove price controls on generic and non-prescription drugs. The extent to which price controls for in-patent products are relaxed will depend on the alternative treatments available. For example, a company that produces a new drug for which there are no existing alternatives is in a strong position. In this situation, liberalisation could result in higher prices for patients and health care systems.

The success of the EU's actions remains to be seen, especially amidst growing pressures on countries to cut expenditure on public health, a lack of effective mechanisms for setting the price of new pharmaceuticals, delays before new products reach some parts of the European market, and the enlargement of the EU to countries with relatively low per capita incomes. In addition, the EU has failed to tackle the effect of the increasingly prevalent use of electronic commerce via the internet.

## ***The Write Stuff***

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### ***Can Europe Become One?***

Will the disharmony of European cultures block the path to a unified Europe? Even if the EU achieves its goals for the pharmaceutical industry, can one Europe be sustained? Over a millennium ago, the Roman Empire collapsed, leaving Europe fragmented into petty states. But culture, technology, economics and politics have progressed. On the eve of the next millennium, the stage is set for Europe to become one.

#### **UK DRUG PRICE REDUCTIONS**

Prices of brand prescription medicines were cut by 4.5% in a new UK scheme effective from the 1<sup>st</sup> October 1999 to reduce pressures on the National Health Service (NHS).

The price cuts apply to all UK or other EU market-authorized brand medicines supplied to the NHS. The UK pharmaceutical industry reluctantly agreed to the cuts but recognised the benefits of the scheme. Competitiveness of the industry in the world market will be improved, so that £7 million a day can continue to be invested in the research and development of new medicines.

#### **UK FACTS**

The NHS:

- drugs bill is £5-£6 billion per year (about 25p per person per day).

The UK pharmaceutical industry:

- invests 20% of its turnover in UK research and development (£2 billion),
- exports £5 billion; imports £3 billion; leading to a trade surplus of £2 billion,
- creates 300,000 jobs,
- saves the NHS £10 billion a year due to decreased hospital admissions,
- pays £400 million Corporation Tax to the government,
- funds half the cost of all General Practitioner further education and training,
- provides £100 million support to academia,
- developed 7 out of the current top 25 medicines world-wide.

The UK spends half that of France or Germany on medicines per person.

The UK is the largest user of generic medicines in Europe but the lowest user of new medicines.

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