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Europe After 1992: Implications For Pharmaceuticals
by M.L. Burstall

On 1 January 1993, the single European market will come into existence. What will this mean for the pharmaceutical companies now operating in Europe? What will it mean for European health care systems and patients of those systems? In this Commentary, I suggest some possible answers. I describe the pharmaceutical market of the European Community (EC); analyze the role of EC countries and agencies in the pharmaceutical industry, with special emphasis on recent developments at the EC level; and describe current initiatives in two key areas of official regulation: drug approval and drug price control. Finally, I identify the gains and losses for the industry, health care systems, and patients from the advent of a unified European market.

Pharmaceutical Use In Europe

In 1988, pharmaceutical expenditure within the EC countries was approximately $38 billion (U.S.) at manufacturers’ prices (Exhibit 1). Five countries-France, the Federal Republic of Germany, Italy, Spain, and the United Kingdom-accounted for 40 percent of this total. Drugs used in hospitals made up 13 percent of the whole; those prescribed by physicians working elsewhere, 75 percent. Over-the-counter sales formed no more than 12 percent of the EC market. From a macroeconomic perspective, spending on all kinds of pharmaceuticals was 10.5 percent of total expenditure on health care and about 0.8 percent of gross domestic product (GDP).1

The EC drug market is substantially larger than that of either the United States or Japan. However, it is far from unified. As Exhibit 1 shows, per capita consumption varies markedly from one member nation to another. These variations arise in part from differences in national

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### Exhibit 1
Pharmaceutical Consumption In The European Community (EC), 1988

<table>
<thead>
<tr>
<th></th>
<th>Total spending&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Per person</th>
<th>Percent of GDP</th>
<th>Percent of total health spending</th>
<th>Percent growth 1982-1986&lt;sup&gt;b&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belgium</td>
<td>$1,210</td>
<td>$123</td>
<td>0.76%</td>
<td>10.2%</td>
<td>7%</td>
</tr>
<tr>
<td>Denmark</td>
<td>450</td>
<td>87</td>
<td>0.40</td>
<td>6.0</td>
<td>19</td>
</tr>
<tr>
<td>France</td>
<td>8,790</td>
<td>158</td>
<td>0.84</td>
<td>11.0</td>
<td>32</td>
</tr>
<tr>
<td>Germany</td>
<td>9,380</td>
<td>153</td>
<td>0.80</td>
<td>8.8</td>
<td>3</td>
</tr>
<tr>
<td>Greece</td>
<td>420</td>
<td>42</td>
<td>0.76</td>
<td>16.5</td>
<td>-3</td>
</tr>
<tr>
<td>Ireland</td>
<td>190</td>
<td>54</td>
<td>0.66</td>
<td>8.9</td>
<td>0</td>
</tr>
<tr>
<td>Italy</td>
<td>7,730</td>
<td>135</td>
<td>0.96</td>
<td>14.3</td>
<td>37</td>
</tr>
<tr>
<td>Netherlands</td>
<td>1,030</td>
<td>69</td>
<td>0.45</td>
<td>5.3</td>
<td>41</td>
</tr>
<tr>
<td>Portugal</td>
<td>600</td>
<td>57</td>
<td>1.11</td>
<td>16.9</td>
<td>37</td>
</tr>
<tr>
<td>Spain</td>
<td>2,470</td>
<td>63</td>
<td>0.73</td>
<td>14.5</td>
<td>-1</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>5,410</td>
<td>89</td>
<td>0.67</td>
<td>10.2</td>
<td>21</td>
</tr>
<tr>
<td>EC total</td>
<td>37,680</td>
<td>113</td>
<td>0.80</td>
<td>10.5</td>
<td>19</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Percent through hospitals</th>
<th>Percent through physicians</th>
<th>Percent over-the-counter</th>
<th>Average cost&lt;sup&gt;c&lt;/sup&gt;</th>
<th>Volume per person&lt;sup&gt;d&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belgium</td>
<td>12%</td>
<td>71%</td>
<td>17%</td>
<td>$8.7</td>
<td>$125</td>
</tr>
<tr>
<td>Denmark</td>
<td>17</td>
<td>65</td>
<td>18</td>
<td>122</td>
<td>62</td>
</tr>
<tr>
<td>France</td>
<td>11</td>
<td>80</td>
<td>9</td>
<td>69</td>
<td>202</td>
</tr>
<tr>
<td>Germany</td>
<td>16</td>
<td>67</td>
<td>17</td>
<td>133</td>
<td>101</td>
</tr>
<tr>
<td>Greece</td>
<td>15</td>
<td>70</td>
<td>15</td>
<td>72</td>
<td>52</td>
</tr>
<tr>
<td>Ireland</td>
<td>13</td>
<td>77</td>
<td>10</td>
<td>132</td>
<td>36</td>
</tr>
<tr>
<td>Italy</td>
<td>13</td>
<td>81</td>
<td>6</td>
<td>87</td>
<td>136</td>
</tr>
<tr>
<td>Netherlands</td>
<td>15</td>
<td>72</td>
<td>12</td>
<td>129</td>
<td>47</td>
</tr>
<tr>
<td>Portugal</td>
<td>10</td>
<td>85</td>
<td>5</td>
<td>78</td>
<td>65</td>
</tr>
<tr>
<td>Spain</td>
<td>12</td>
<td>76</td>
<td>12</td>
<td>73</td>
<td>76</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>15</td>
<td>69</td>
<td>16</td>
<td>118</td>
<td>66</td>
</tr>
<tr>
<td>EC total</td>
<td>13</td>
<td>75</td>
<td>12</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

Source: Author’s calculations, based on data from national sources and from the European Federation of Pharmaceutical Industry Associations. Price indices are from G. Sermeus and G. Andriaenssens, Drug Prices and Drug Legislation in Europe (Brussels: BEUC, 1989).

<sup>a</sup> Millions of U.S. dollars; at manufacturers’ prices.

<sup>b</sup> Deflated by the gross domestic product (GDP) deflator.

<sup>c</sup> Manufacturers’ prices in index form, where EC average equals 100.

<sup>d</sup> Per person consumption in U.S. dollars, divided by price index and reduced to an index, where EC average equals 100.

Wealth and population: large, rich countries consume more than small, poor ones. Populations’ age structure is also a significant factor: the young and the old require more treatment than do those of working age. However, the differences between European countries cannot be wholly explained in these terms. In relation to GDP, per capita consumption is unexpectedly high in Belgium, France, Italy, and Spain and unexpectedly low in Denmark, the Netherlands, and the United Kingdom. When allowance is made for differences in average prices, the contrasts become...
even more striking. The volume of consumption in Belgium is approximately 2.5 times that in the Netherlands, even though the two countries share a common border. Such contrasts are not new; evidence suggests that they have persisted for many years. Other factors must therefore be involved, such as differing popular attitudes about medicine and differing medical cultures among EC nations. One result of the latter is large national differences in physicians’ prescribing behavior, especially in the treatment of minor illnesses, which in every country account for the bulk of consultations. Thus, for example, 88 percent of all consultations in Belgium result in a prescription, but only 50 percent of those in the Netherlands do. To develop pan-European policies is therefore not easy. This is especially true of actions that affect the nature and volume of pharmaceutical consumption.

Role Of National Governments

As in all developed countries, the European pharmaceutical industry is subject to an unusual degree of government control. Government action has a powerful influence on innovation, manufacturing, marketing, distribution, trade, and profits. Also, European governments use their regulatory power to attain specific goals in the pharmaceutical market. Two of the most common goals are cost containment and research and development in the industry.

Cost containment. All European governments are concerned with limiting public expenditure on pharmaceuticals (Exhibit 2). In every EC country, the state or statutory national insurance agencies pay most of the health care bill, which has risen steadily in recent years. Governments therefore seek ways to economize; for obvious political reasons, drug spending is the first and favorite target. Economy measures vary from country to country. Both positive lists—which limit reimbursement to specified products—and negative lists—which exclude particular products or classes of product from reimbursement—are common. In all countries, the patient is expected to pay some part of the bill, although exemptions are common for the old, the chronically ill, and the hospitalized. Most member nations control the prices of individual medicines; the main exceptions to this are the United Kingdom, which controls profits; Germany and the Netherlands, which limit reimbursement for many drugs to a flat rate; and Denmark, which, uniquely, permits a free market. Generics are promoted in all EC countries, although generic substitution is permitted only in Germany.

Research and development. Most regulation of pharmaceuticals, related to both cost and innovation, still takes place at the national level.
## Exhibit 2
Methods Of Controlling Pharmaceutical Expenditure In The European Economic Community, 1989

<table>
<thead>
<tr>
<th></th>
<th>Positive list</th>
<th>Negative list</th>
<th>Patient copayment system</th>
<th>Percent met by patient</th>
<th>Generics promoted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belgium</td>
<td>Yes</td>
<td>Yes</td>
<td>0/25/50/60% of price</td>
<td>35%</td>
<td>Yes*</td>
</tr>
<tr>
<td>Denmark</td>
<td>Yes</td>
<td>No</td>
<td>25/50/100% of price</td>
<td>33</td>
<td>Yes</td>
</tr>
<tr>
<td>France</td>
<td>Yes</td>
<td>No</td>
<td>0/30/40/100% of price</td>
<td>30</td>
<td>Yes*</td>
</tr>
<tr>
<td>Germany</td>
<td>No</td>
<td>Yes</td>
<td>Flat rate</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>Greece</td>
<td>Yes</td>
<td>No</td>
<td>20% of price</td>
<td>N/A</td>
<td>Yes</td>
</tr>
<tr>
<td>Ireland</td>
<td>No</td>
<td>Yes</td>
<td>Varies with patient</td>
<td>N/A</td>
<td>Yes</td>
</tr>
<tr>
<td>Italy</td>
<td>Yes</td>
<td>No</td>
<td>30 or 40% of price plus</td>
<td>32</td>
<td>Yes*</td>
</tr>
<tr>
<td>Netherlands</td>
<td>No</td>
<td>Yes</td>
<td>Flat rate</td>
<td>20</td>
<td>Strongly</td>
</tr>
<tr>
<td>Portugal</td>
<td>Yes</td>
<td>No</td>
<td>0/20/50% of price</td>
<td>25</td>
<td>Yes</td>
</tr>
<tr>
<td>Spain</td>
<td>Yes</td>
<td>Yes</td>
<td>40% of price</td>
<td>25</td>
<td>Yes</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>No</td>
<td>Yes</td>
<td>Flat rate</td>
<td>10</td>
<td>Strongly</td>
</tr>
</tbody>
</table>


*With reservations.*

The Treaty of Rome, which is the basic law governing the European Community, says nothing about the organization and financing of health care systems. Each country has developed its own system, the basic principles of which may go back many years. For example, Germany’s system originated under Bismarck, and that of the United Kingdom, under the Liberal government of 1911. Moreover, the fact that regulation is under national control means that governments can bend the rules for their own ends. For example, a regime that wishes to build up a national pharmaceutical industry may reward investment by allowing better prices for new medicines or price increases for existing ones. A number of EC countries—notably France—have followed such policies. Most international companies have been forced to build up production and research facilities in several European countries as a condition of operation, with substantial losses in economies of scale and increased costs.  

National regulation of the pharmaceutical industry therefore has distorting effects on the European pharmaceutical market and on the operations of the pharmaceutical industry within Europe. How might this change after 1992?

### Role Of The European Community

The European Community is not as yet a federal state. Although health care in general remains a matter for the individual EC member nations,
the Treaty of Rome has already had a substantial, if perhaps unexpected, impact on the regulation of the European pharmaceutical industry.

Under the treaty, as modified by the Single European Act of 1987, the aim of the European Community is to establish a unified European market without internal frontiers (Article 8a). Certain articles are of particular relevance to the pharmaceutical sector. (1) Quantitative restrictions on imports and all measures having that effect are forbidden (Article 30), but such restrictions on the grounds of health and intellectual property (among others) may be permissible (Article 36). (2) Agreements that affect trade or restrict competition within the European Community are void unless they can be shown to promote technical and economic progress while benefiting the consumer (Article 85). (3) Abuse of a dominant market position is forbidden (Article 86). (4) Forms of state aid that distort competition by favoring particular undertakings or the production of certain kinds of goods are inadmissible insofar as they affect trade between member nations, unless they have certain specific social roles (Article 92).

The European Commission, the EC governing body, began to issue directives concerning the pharmaceutical industry in 1965 and has continued to do so at intervals ever since. Its aim has always been to remove obstacles to the treaty’s purposes by eliminating national requirements that might impede trade between the member states. Much of this work has been uncontroversial. The commission has tried to engineer the largest possible level of agreement among all the parties and has been willing to approach its objectives step by step. Simultaneously, a body of case law has been built up through actions heard before the European Court of Justice—the supreme court of the European Community—whose decisions are binding upon the member nations. The court has consistently given priority to Article 30 of the treaty over all other articles and has held that it applies to all measures capable of hindering trade within the European Community, whether directly or indirectly.

The ratification of the Single European Act accelerated this process of gradual harmonization. With a clear deadline of 1 January 1993, the commission submitted a range of proposals intended to complete unification of the EC pharmaceutical market, some of which have been adopted and others of which are under discussion. These include measures that touch on two key areas of concern: drug safety and drug pricing.

Drug Safety

The most important determinant of drug safety is the process by which new products are admitted to the market. Other pertinent areas of
regulation are classification of drugs as prescription-only or over-the-counter, the provision of patent information with medicines, and the obligations of pharmaceutical wholesalers. All of these are the subject of draft directives by the commission.

At present, a new pharmaceutical product must receive permission from a national government before it is allowed in a national market. This applies not only to genuinely novel medicines but also to drugs based on known ingredients or to generics. Each EC country has its own regulatory body and, indeed, its own ideas about evaluation. Clearly, this results in a considerable duplication of effort, even though all EC nations have for many years provided abbreviated forms of application for copy products. In practice, the extra costs have been modest although not entirely negligible. International companies must sell their products worldwide and generally choose to evaluate their new medicines with the U.S. Food and Drug Administration (FDA) in mind. Accordingly, they prepare a master dossier from which their applications to particular countries are drawn, a process that constitutes an appreciable burden on the industry. More important, differences in national methods of drug approval and, even more, in the time taken to approve applications constitute a barrier to trade within the European Community.

The commission has taken a number of steps to ease the path to marketing approval. First, it standardized, to a considerable degree, the information and forms of documentation required. Second, it introduced in 1979 a system of mutual recognition of new products, which was extensively modified in 1986. Under this system, a company that had obtained marketing authorization in one member nation could be granted reciprocity by other member states to which it had applied within 120 days, unless a “reasoned objection” was made within that time. If such an objection was made, it was referred to the Committee for Proprietary Medicinal Products (CPMP)—whose members are from the European Community and the commission—for consideration. The CPMP would issue an opinion to be considered by the states involved; the states would be obliged to give a final “yes” or “no” within sixty days.

This approach has met with extremely limited success. Only one application failed to attract reasoned objections, and, even after the CPMP gave its opinion, prolonged delays—up to twenty-seven months in one case—followed before the final decision was made. The central problem has been the widespread if rarely expressed doubts about the comparability of national standards and the reluctance of national regulatory bodies to cede ultimate control. Undaunted, the commission began the preparation of a further directive about marketing authorization in 1988. Early discussions revealed strong support for a unified procedure
but also considerable division of opinion about what the procedure should be. The governments of France, Germany, Italy, the Netherlands, and Spain, together with the pharmaceutical industry federations of France, Germany, and the United States, favored binding mutual recognition of national decisions. The governments of Denmark, Ireland, and the United Kingdom inclined, with reservations, toward a major role for a central agency—a European FDA, as its enemies called it—as did the British industry federation and the powerful pan-European consumer association, BEUC.

The latest drafts of the commission, which are now undergoing the long and complicated process of approval, represent an ingenious attempt to reconcile these opposing points of view. A threefold system of approval is proposed. At the risk of oversimplification, this may be described as follows: (1) In the case of new active substances, a company could apply directly to a central body—the Medicines Evaluation Agency (MEA), in effect a reinforced version of the existing CPMP—which would in addition have sole jurisdiction over products developed through biotechnology. (2) Alternatively, a company with a new active substance could apply to a single member state; approval by the latter would entail binding mutual recognition by all other member countries. In the case of disagreement between states, the application would be submitted to the MEA, who would advise the commission as to a final decision. (3) Generics, line extensions, and other medicines of purely local interest would continue to be dealt with by national authorities. The commission anticipates that most applications to market new active substances would go through the second “decentralized” procedure, which would also deal with other “products of general interest.”

A most important point concerns the mechanism by which approval decisions will be made binding on member states. This must obviously involve some erosion of national sovereignty, which has always proved a delicate matter within the European Community. Current proposals emphasize that the right to make such decisions must remain with the commission or the Council of Ministers. It cannot in EC law be delegated to the MEA, whose role is advisory, although it is clearly hoped that the MEA will be able to resolve all questions of a purely scientific nature. After the MEA has made its recommendation, it will be up to the commission to prepare a draft decision for submission to the Council of Ministers, “taking into account the objectives of Community and considering all relevant information.” This proviso could open the door to a wide range of nontechnical considerations, some of which, such as the need for a new product, might have negative implications for the industry.

It is difficult to know how well this threefold system will work after
1992. All interested parties are not yet convinced that the standards set by some national registration authorities are generally acceptable. Consumer groups in particular are concerned about this issue and are naturally pressing for leveling up rather than down. They would prefer one central pan-European agency along the lines of Britain’s Medicines Control Agency. At least in private, their doubts are shared in some official circles. It would not be surprising if the MEA found itself dealing with an unmanageably large number of appeals arising from the decentralized procedure. Some observers have speculated that the proposals are intended to determine once and for all whether mutual recognition can ever work or whether a European FDA is the only way forward. There must also be doubts about the time frames laid down, which, according to past experience, seem highly optimistic.\(^\text{10}\)

<table>
<thead>
<tr>
<th>Prices And Price Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>Despite these reservations, it is probable that a unified system of marketing authorization will be in place within the next few years. Much less progress has been made on the second major area of concern: prices and price controls.</td>
</tr>
<tr>
<td>As discussed above, national regulation of the pharmaceutical industry has distorting effects on the market. One effect is the covert use of pricing policies to reward local investment. Another is parallel trade. Entrepreneurs buy drugs where they are cheap and export them to where they are expensive. There they are sold at cut rates to pharmacists, who, of course, are reimbursed at the local list price by the health care agency. Traders and pharmacists gain; manufacturers lose. As yet, the scale of this practice is small and amounts to no more than 1 to 1.5 percent of European sales. In the United Kingdom and the Netherlands—both high-price countries—this figure is as high as 5 to 10 percent. The pharmaceutical industry is seriously concerned about parallel trade, even though it is still a potential rather than an actual threat in most countries.(^\text{11})</td>
</tr>
</tbody>
</table>
| In the future, the scope of parallel trade might increase. The main problem for traders has been to obtain reliable supplies. Other considerations, such as the need to relabel products, are of little importance. Most wholesalers still operate on a national rather than on a pan-European basis. In a unified market, this could change. Wholesalers themselves might supply all of their customers from the cheapest source. In a worst-case scenario, downward pressure on prices could therefore become irresistible, with serious consequences for the European research-based pharmaceutical industry. Under EC law, the parallel trader is in a strong position. In a long series of cases heard from 1975 onward, the European
Court of Justice held that even though the price differences that make parallel trade worthwhile are the result of government actions, the trade itself is legal within very broad limits, and neither governments nor companies can take action against it.  

Companies would therefore much prefer pan-European prices, provided that they were at a "reasonable" level. Some have urged that prices everywhere should be free, arguing that competition would prevent them from rising excessively. Governments and health care agencies are naturally less keen on this approach; they see it as giving a blank check to the industry. Some argue, reasonably enough, that low prices are a result of low incomes; to raise prices to the European average would be to impose an intolerable burden on public health care systems. In France, a wealthy country with very low prices, the rationale is different. For cultural reasons, the French have an insatiable urge to take drugs, and prices must be kept low so as not to bankrupt the national insurance system. In any case, large volume compensates for low prices and makes France attractive to the drug companies.

The European Commission has approached the question of prices and pricing policies cautiously. As emphasized above, it has no powers over national regulations except insofar as they contravene the Treaty of Rome. The European Court of Justice has held that national price controls and negative lists are legal per se. The instances in which the commission has considered price-related issues have therefore all turned on the issue of free trade. The former Italian cost-plus pricing scheme was struck down because allowable research costs were increased for drugs developed entirely in Italy, thereby giving an unfair advantage to Italian firms. Similarly, the Belgian incentive scheme, which openly awarded price increases to companies in return for investment in Belgium, was successfully attacked and subsequently abandoned.

The commission's first thoughts about pricing policies are suggested by a communication made in 1986 in connection with the completion of the single European market. National cost control measures with the aim of offering the best possible care to all citizens without excessive cost to the public purse were declared to be compatible with the Treaty of Rome. Prices must be realistic and arrived at by explicit calculation. Criteria for negative lists must be objective. Price and profit freezes are permissible but must be nondiscriminatory.

In January 1990, the Price Transparency Directive came into force, laying down in detail what the commission meant by these statements. Under the directive, EC countries must publish details of the systems they use to classify products for reimbursement, to fix prices and profits, and to operate positive and negative lists. Approval or disapproval of prices
or price increases proposed by pharmaceutical companies must take place within 180 days. If such a proposal is rejected, then the applicant must be given a statement of the reasons based on “objective and verifiable criteria.” In the absence of such a decision, the company is entitled to apply its price forthwith. Price freezes must be reviewed annually. A data bank of prices is being set up to provide information about 2,500 top-selling medicines in the European Community.

As yet, there has been insufficient time to judge the effects of the Transparency Directive. By itself, it is unlikely to lead to a convergence of national prices. Governments are still able to regulate prices and profits, provided they are open about how they do so. The directive might reveal the use of price concessions as incentives. However, a company or companies that felt they had been treated unfairly would have to take the initiative. To take such a step would require considerable forethought. A successful legal action—still more, an unsuccessful one—could permanently sour relationships between the company and its monopsonistic national customer. The element of risk would be considerable.  

However, the Transparency Directive is not the commission’s last word on this subject. The directive includes an article requiring the commission to submit to the Council of Ministers, by 31 December 1991, a proposal on appropriate measures for abolishing any remaining barriers to or distortions of the free movement of medicines. To this end, the commission has recently circulated a discussion document on pricing and reimbursement. The document raises a number of questions: Is it necessary to control the prices of nonreimbursed drugs? In the case of reimbursed medicines, is it necessary to control prices directly, or should such control be exercised indirectly via admission to reimbursement? If price controls are necessary, should the criteria used to fix a price be specified? Would an EC system of profit control be desirable? Should there be a common therapeutic classification of drugs? These are but the most important queries.

Moves in these directions could lead to a considerable extension of control by the European Community over what has hitherto been a national responsibility. Although the wording of the discussion document is tentative, the thinking behind it clearly envisages a greater degree of harmonization of pricing and reimbursement than exists at present. The flow of the argument is in this direction. Thus, having raised the question of a pan-European system of therapeutic classification, the document goes on to ask if it would be desirable to define at the EC level those categories that should benefit from reimbursement and whether there should be pan-European reimbursement levels for such categories. It is difficult not to believe that some of these questions are phrased in such a way as to
elicit a positive answer.

How acceptable such proposals might be is a matter of opinion. I think, however, that a consensus view is unlikely to emerge rapidly. The interests of the major parties involved are far from the same. The research-based industry would welcome free pricing and might tolerate profit controls; most companies—there is some division of opinion—would oppose flat-rate reimbursement on the Dutch or German models. On the whole (generalization is difficult), manufacturers prefer full reimbursement with the patient paying a proportion of the cost. Governments and national health care agencies are primarily concerned with controlling drug costs. They might consider free pricing if it were accompanied by effective and politically acceptable ways to limit expenditure. Patients are accustomed to getting most of their medicines below cost; they respond negatively to attempts to limit this right.18

Looming behind these divergences is the problem of national sovereignty. Constructing the European Community has meant that all member nations have had to cede some of their powers to Brussels, but they have often done so with bad grace. To harmonize pharmaceutical pricing and reimbursement, even approximately, would be to force member countries to relinquish national control over large amounts of money. The prolonged discussions over a European system for the registration of new medicines suggest that, even when financial matters are not at stake, agreement can be difficult to engineer. How much more difficult will be the road to common pricing.

Possible Outcomes

Realizing a unified EC market is a complex process that will be far from complete on 1 January 1993. The outcome will depend on how, as well as to what extent, unification is achieved. For example, the consequences of pan-European reimbursement would be different if a flat-rate payment rather than a proportion of the cost price were made mandatory. That said, however, it is possible to suggest the dimensions of some of the developments of the near future.

As far as issues of drug safety are concerned, it is probable that a unified system of product registration will benefit all parties. Pharmaceutical companies will save money by not having to file duplicate applications with twelve different national bodies. They will also gain if the new procedures are more rapid than those currently in force, although this is less certain. Patients will also benefit from a more rapid drug approval process in that they would have quicker access to new products. If methods of assessment remain adequate, patients will neither gain nor
lose. Health care systems, however, might suffer in that pharmaceutical expenditure will rise, because new drugs, although often better, are always more expensive. ¹⁹

The impact of pan-European pricing and reimbursement is likely to be much more problematic. The Transparency Directive could benefit pharmaceutical companies as a whole, in that it would make for a "level playing field" in which the market was no longer distorted by covert subsidies. In the longer run, the directive might aid the concentration of facilities, as companies would no longer feel obliged to maintain production in most EC countries. Cost savings would be appreciable and would be concentrated in multinational firms, especially those of the United States and Switzerland. However, this would be a slow process. Given the political problems of withdrawal, plants would not be shut down until they became obsolete, which might not be for many years. ²⁰

It should also be emphasized that not all companies would profit from such changes. The "level playing field" favors the stronger players. The weaker firms—those of France, Italy, or Spain, for example—would suffer. When governments bend the rules, local companies benefit more often than not. This is natural; such firms have larger local investments and activities and a greater commitment to their country of origin. Governments often see local firms as important national assets whose well-being should be ensured. This will become more difficult under the Transparency Directive. After 1992, the most competitive companies—those of Germany, Switzerland, the United Kingdom, and, above all, the United States—will likely dominate even more than they do now.

Health care agencies and patients have less to gain or to lose from the directive. In the absence of price concessions, prices might fall, but, of course, it is often these concessions that make a national market particularly attractive. The concentration of facilities might reduce costs, but it seems doubtful that such savings would be passed on to consumers. The tendency is for multinational companies to integrate their worldwide operations, and very detailed costing would be required to reveal the potential savings made to, say, Britain’s National Health Service (NHS) due to the closure of a plant in Greece.

In any case, the sums involved, although important to companies, would have less effect on levels of taxation or health insurance contributions. A change of 10 percent in the drug bill, which would have a considerable impact on company income and still more on profits, would alter health care expenditure by 1 percent, or national expenditure by less than 0.1 percent. Only in Portugal and Greece would this proportion be exceeded. ²¹

The effects of pan-European pricing or reimbursement are even more
hypothetical. Health care agencies likely will continue to exert downward pressure on pharmaceutical expenditure. All EC nations have recently taken further steps in this direction, shifting an increasing proportion of the cost onto patients by raising patient copayments and reducing the range of drugs reimbursed. Other approaches receiving increased attention are fixed-rate reimbursement, increased use of generics, and direct pressure on physicians. Such actions are as yet at the national level and independent of any initiatives of the European Commission.

Nevertheless, it is conceivable that a consensus in favor of freer pricing might eventually emerge. The problems to be overcome are obvious. Transitional arrangements would have to be made for the poorer member countries. This might involve a system of rebates. Freer prices would be the *quid pro quo* for concessions by the pharmaceutical companies—perhaps the general introduction of generic substitution, which is still illegal except in Germany. Whatever mixture or mixtures of reimbursement and copayment are adopted, special provisions for the old and the chronically ill will have to be made.

**Conclusions**

It is difficult to know now what the European pharmaceutical scene might look like after 1992. It is unlikely, however, that the unification of the pharmaceutical market will be completed on schedule. In this respect, project 1992 is not an event but a process, one that is likely to continue for years to come.

Nevertheless, it seems likely that whatever system emerges will differ significantly from that of the past. Many aspects of official regulation will become more uniform within Europe; this will certainly be true of drug safety issues. The outlook concerning the control of expenditure is less clear. Here the objectives of the European Community intersect with the desire of all member states for increased economy, and it is difficult to predict, from the wide range of options currently available, which, if any, will prevail.

The immediate gains from the single market are likely to be relatively modest and spread in a complex way among the various players. Many key issues that might affect the outcome are still to be decided. In the longer run, a substantial redistribution of competitive strengths among companies and countries is probable. From the standpoint of the consumer, whether national or individual, the single market could lead to either gains or losses of welfare. Only time will tell.
NOTES


2. A linear regression of per capita pharmaceutical spending against per capita GDP for the eleven EC countries (Luxembourg is included with Belgium) in 1987 gave a correlation coefficient of 0.72, suggesting that about half of the variance between nations could be accounted for by differences in national income. Inclusion of a dummy variable to represent differing traditions of medical practice raised the coefficient to 0.89. Similar results were obtained for 1975.

3. A pioneering general study is L. Payer, *Medicine and Culture* (London: Gollancz, 1990), which compares the practice of medicine in France, Germany, the United Kingdom, and the United States. The numbers of prescriptions per consultation are from the Belgian organization Pharmaca, as reported in *Scrip* 1557 (10 December 1990): 7.


6. The suprenne policy-making body of the European Community is the Council of Ministers, but new laws originate in practice with the European Commission. Under the Single European Act, the European Parliament has powers to approve, reject, or amend—though not to initiate—legislation. From the standpoint of the pharmaceutical sector, Directorate-General III of the commission is the most important part of the system, although several other directorates-general also play a significant part. Directives issued by the European Community are binding on the member nations as regards objectives, but how they will incorporate the particular purpose into national law is left to the national authorities.

7. Burstall and Reuben, *The Cost of Fragmentation*, 52-67. The additional costs due to the need for multiple applications were estimated at 0.5-0.8 percent of total costs.

8. This procedure was introduced under Directive 75/319 of 1975 and modified by Directive 83/570 of 1983. Only fortyone products, none of first importance, used the original procedure between 1979 and 1986, but 124 used the modified procedure between 1986 and July 1990.


10. In the centralized procedure, a period of 2 10 days for the technical staff of the MEA to evaluate the proposal is allowed. In the decentralized procedure, the national authority to which application is made is also given 210 days to reach a decision, after which the other member states have 120 days to follow suit. In the case of disagreements between states, a period of 120 days for resolution of the dispute is laid down, after which the matter is revoked to the MEA, whose scientific, though not administrative, decision is binding. Other shorter time limits are specified for the later stages of the procedure. Current national registration procedures take a year or more in most member countries for products of any significance, although a uniform time of 210 days was specified by the commission in 1975. The present system of nonbinding mutual recognition is supposed to produce a decision within 120 days “unless a reasoned objection [from another member state] is forthcoming.” Reasoned objections always have been forthcoming. The appeals system built into the proposed decentralized procedure could
stretch the period of evaluation to eighteen to twenty-four months.

11. For estimates of the extent of parallel trade in the community, see M.L. Burstall, *The Market for Parallel Imports* (Paper presented at the conference, Generics and Parallel Imports-Threat within or Major Challenge?, organized by Nicholas Hall and Company, 27-28 March 1990). Governments and national health care agencies benefit to the extent that they can share in the savings through parallel trade. In the United Kingdom, the overall remuneration of pharmacists under the NHS has been reduced to take account of the practice; in the Netherlands, the health insurance agency takes 70 percent of the savings.

12. The key cases were ECJ 15/74: Centrafarm BV and others versus Sterling Drug Inc.; 16/74: Centrafarm BV versus Winthrop BV; 102/77: Hoffmann LaRoche versus Centrafarm BV, and 1/81: Pfizer Inc. versus Eurimpharm. Interviews with parallel traders (Burstall, unpublished) show that supply problems are by far the largest problem for them. It is cheap, easy, and legal to paste a new label onto an existing pack; the author takes Zyloric and has received packs printed in Greek, Spanish, and Portuguese during the past year.

13. Based on numerous conversations of the author with senior officials in European countries and with executives of transnational pharmaceutical companies.

14. The cases mentioned were respectively ECJ 181/82: Roussel and others versus Netherlands; 238/82: Duphar and others versus Netherlands; and 56/87: European Commission versus Italy. The Oleffe law which set up the Belgian system of incentives, expired at the end of 1988 and was not renewed. Pressure to this end was exerted by the commission.

15. In EC parlance, a *communication* is a strong recommendation rather than a binding rule. The communication in question was *Communication on the Compatibility with Article 30 of the Treaty of Measures taken by Member States Relating to Price Controls and Reimbursement of Medical Products* (C[86] 1723; Official Journal C 310/7). The Transparency Directive is *Directive Relating to the Transparency of Measures Regulating the Pricing of Medicinal Products for Human Use and Their Inclusion within the Scope of National Health Insurance Systems* (COM[88]23; Official Journal L40).

16. A view confirmed by executives of multinational companies in conversations with the author.


18. As evidenced by the outcry against the recent French proposal to eliminate the category of medicines carrying 40 percent reimbursement. Most of these products are “comfort” drugs of marginal therapeutic significance.


21. Value added by the pharmaceutical industry in the various EC countries is in the range of 30-50 percent of sales (Eurostat, *Structure and Activity of Industry*, Table 257, various issues).