

April 1996

# EUROPEAN UNION DRUG APPROVAL

## Overview of New European Medicines Evaluation Agency and Approval Process







United States  
General Accounting Office  
Washington, D.C. 20548

Health, Education, and  
Human Services Division

B-261605

April 5, 1996

The Honorable Nancy Landon Kassebaum  
Chairman, Committee on Labor and  
Human Resources  
United States Senate

Dear Madam Chairman:

The movement toward uniting individual European countries into a single marketplace has made the European Union (EU) the largest pharmaceutical market in the world.<sup>1</sup> With a population of about 370 million, the EU represents a consumer base that is one-third larger than that of the United States. Moreover, the EU leads the world in the consumption of pharmaceutical products, using \$82.7 billion worth of pharmaceutical products in 1992, while the United States used about \$54.8 billion.<sup>2</sup>

As part of its ongoing effort to establish a single European market for pharmaceuticals, the EU recently modified its drug approval procedures and created a new agency—the European Medicines Evaluation Agency (EMEA)—to provide a faster and more efficient drug approval process that would benefit consumers and industry.<sup>3</sup> Given the size of the EU market and the recent regulatory changes, advocates of reforming the U.S. Food and Drug Administration (FDA) have suggested that the new European drug approval process may provide some alternative approaches for improving the timeliness of FDA's drug approvals.

To assist your Committee in considering various FDA reform proposals, you asked that we (1) determine how the EU now reviews and approves new drug applications (NDA)<sup>4</sup> and (2) explain why the EMEA was established, how it operates, and how it is financed. Because this report uses European terms that may not be familiar to U.S. readers, we have defined these terms in a glossary at the end of this report.

<sup>1</sup>The European Union, formerly referred to as the European Community, currently consists of 15 countries commonly referred to as Member States. The 15 Member States are Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the United Kingdom.

<sup>2</sup>Eastern Research Group, Inc., Developments in International Pharmaceutical Regulation: Implications for the United States (Lexington, Mass.: Eastern Research Group, Inc., Sept. 12, 1995), pp. 1-2.

<sup>3</sup>The EMEA is also referred to as the European Agency for the Evaluation of Medicinal Products.

<sup>4</sup>The EU refers to its NDAs as marketing authorization applications. However, for the purposes of consistency, this report refers to both types of applications as NDAs.

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To gather this information, we reviewed background documents, legislation, and status reports on the EU drug approval process and interviewed senior officials at the EMEA and the Commission of the European Communities, which oversees the EMEA's activities.<sup>5</sup> We also interviewed representatives from two European-based pharmaceutical companies and two pharmaceutical trade associations, as well as several academics knowledgeable in European pharmaceutical policies. We conducted this study between April 1995 and March 1996 in accordance with generally accepted government auditing standards.

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## Results in Brief

Previous EU regulatory efforts to allow pharmaceutical companies to market their products throughout Europe were unsuccessful because the Commission did not require all Member States to accept the drug approval decisions made by the Commission or other Member States. As a result, the EU enacted legislation in 1993 that created a new approval process. The legislation also made Commission decisions binding on all Member States for both marketing biotechnology and other high-technology products and resolving disputes among Member States concerning drug approval decisions.

The new drug approval process established two new procedures for achieving EU-wide drug approvals—a centralized procedure and a decentralized procedure. Pharmaceutical companies must now use the centralized procedure to obtain approval for biotechnology products.<sup>6</sup> Companies may choose either the centralized or decentralized procedure for other high-technology and innovative products.<sup>7</sup>

At the same time that it established new approval procedures, the Commission created the EMEA to improve the timeliness of new drug approvals and to ensure that biotechnology and other high-technology pharmaceutical products meet the highest standards of safety, efficacy, and quality.

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<sup>5</sup>The Commission of the European Communities is the central regulatory body in the EU that drafts legislation in the form of directives and regulations designed to foster a single market in Europe. The Commission also enforces these rules.

<sup>6</sup>According to Commission regulations, biotechnology products include those derived from recombinant DNA technology, controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes, and monoclonal antibody methods.

<sup>7</sup>According to Commission regulations, other high-technology and innovative products include new delivery systems, new indications, new manufacturing processes that represent significant innovations, and new active substances not previously approved for human use in the EU.

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The new EU drug approval process and the creation of the EMEA represent an important step toward creating a single European marketplace for prescription drugs. However, because the new system has been operational for only a year, it is too soon to determine whether it will enable pharmaceutical companies to more quickly market their products throughout Europe.

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## Background

Since its establishment by the Treaty of Rome in 1957, the EU has tried to create a single market among its Member States to facilitate the free movement of goods, services, capital, and people. As part of this effort, the Commission has attempted to consolidate and harmonize many of the pharmaceutical regulations that have existed among the Member States. Specifically, the Commission established two methods, called the multistate and concertation procedures, allowing pharmaceutical products to be marketed in all the Member States if approved by one Member State. The Commission believed that these methods would promote public health, by making drugs available to patients in a more timely manner, and advance industry interests, by stimulating investment in European research and development activities. However, these initial efforts were not successful because the Commission did not require Member States to accept drug approval decisions made by the Commission or other Member States.

In 1975, the Commission established a multistate procedure to allow a pharmaceutical company to market a product in all Member States if just one of them approved the product application—a procedure referred to as “mutual recognition.” The Commission also created the Committee for Proprietary Medicinal Products (CPMP)<sup>8</sup> to coordinate the Member States’ assessments of pharmaceutical products and arbitrate disputes among the Member States regarding the marketing of pharmaceutical products. However, the multistate procedure was unsuccessful in obtaining mutual recognition of drug approval decisions because at least one Member State raised an objection to every multistate application. Moreover, the CPMP opinions were not legally binding and, as a result, did not resolve disputes among the Member States.

In 1987, the Commission established another process—the concertation procedure—designed to foster a single market. Under this procedure, the CPMP reviewed all biotechnology and other high-technology pharmaceutical products for approval across the EU. The EU decided to

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<sup>8</sup>The CPMP was composed of representatives from each Member State’s national marketing authority.

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centralize the review process for biotechnology and other high-technology products because many of the Member States did not have the scientific expertise needed to review such products. However, only 5 of 30 product applications reviewed under the concertation procedure and approved by the CPMP were authorized for marketing by all the Member States.

Thus, neither the multistate nor concertation procedure achieved the goal of free circulation of pharmaceuticals across all EU Member States because these procedures did not compel the Member States to accept a majority opinion of the CPMP. While the Member States professed allegiance to the principles of mutual recognition, their national regulatory authorities continued to review product applications and render their own opinions before allowing the products to be marketed in their country. Because the CPMP opinions were not binding, Member States issued different decisions on drug approvals, which prevented pharmaceutical companies from obtaining EU-wide approval for their products.

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## New EU System Uses Two Drug Approval Procedures

Under the new EU drug approval process, pharmaceutical companies may use either a centralized or a decentralized procedure to obtain approval to market their pharmaceutical products in more than one Member State using one application.<sup>9</sup> These procedures modify the former multistate and concertation procedures by (1) defining specific review steps and establishing time limits for review processes and (2) requiring Member States to accept as binding, decisions that are issued by the Commission. In addition, the CPMP, which was formally an advisory arm of the Commission, now serves as one of the EMEA's scientific committees.<sup>10</sup> The CPMP, composed of two representatives from each Member State, renders opinions about the safety, efficacy, and quality of human pharmaceutical products that are binding on all the Member States.

Although the new EU drug approval process changes the method for obtaining a marketing authorization, it does not affect drug pricing and reimbursement policies, which remain the responsibility of each Member State. Thus, in order to actually market a pharmaceutical product approved under the new process, manufacturers must still negotiate a product's price with individual Member States.

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<sup>9</sup>Until 1998, pharmaceutical companies have a third option, called the national route, which allows them to seek separate national approvals to market their products in selected Member State(s). This report focuses only on the EU's two primary procedures for drug approvals.

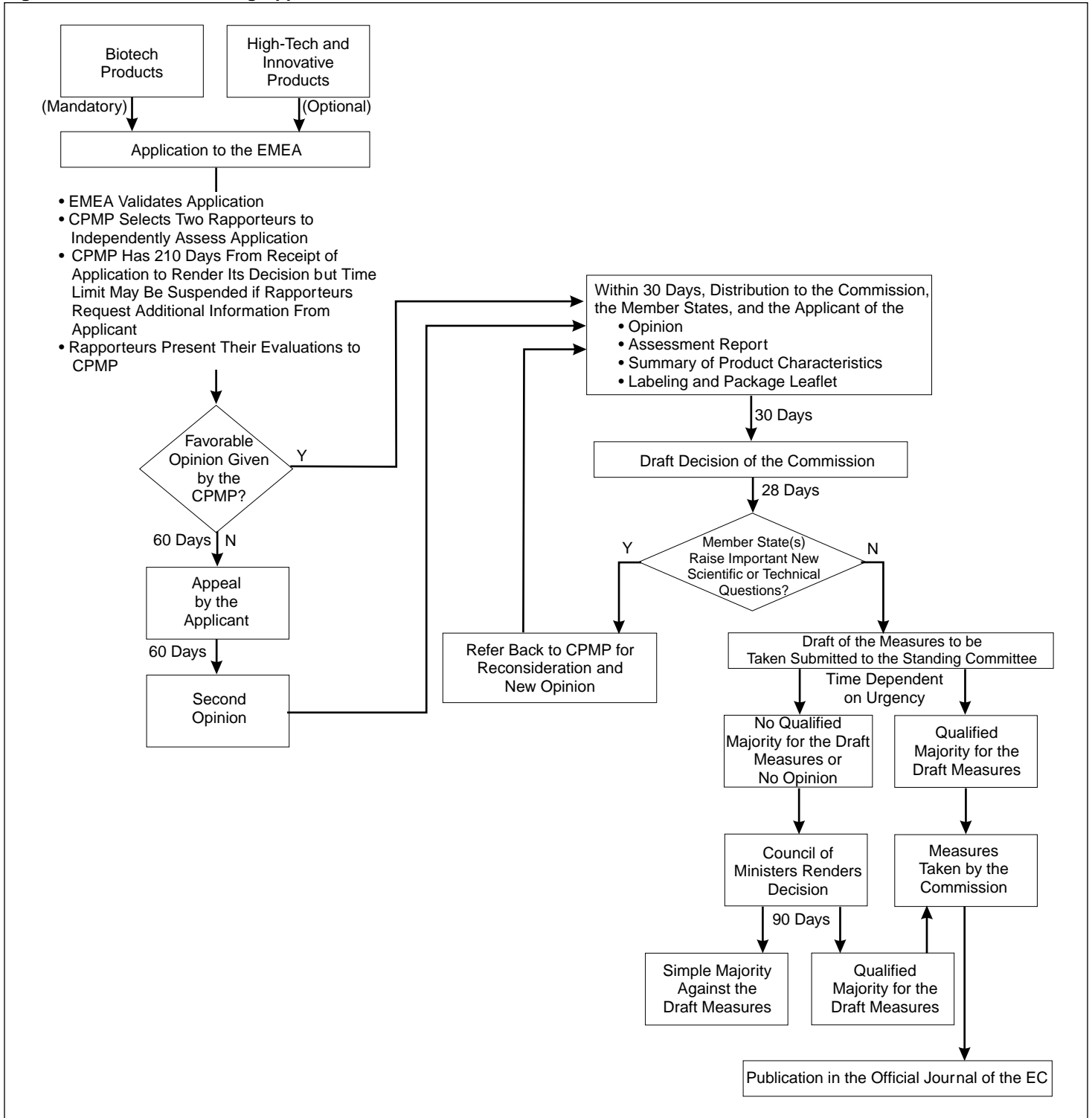
<sup>10</sup>The EMEA's other scientific committee—the Committee for Veterinary Medicinal Products (CVMP)—oversees the scientific evaluation of pharmaceutical products for veterinary use. This report focuses only on the process for reviewing and approving new drugs for human use.

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## The Centralized Procedure

Pharmaceutical companies are now required to use the centralized procedure for biotechnology products and have the option to use it for other innovative products. Under the centralized procedure, Commission approval of a new drug application allows a pharmaceutical company to market its pharmaceutical product in all 15 Member States without having to obtain separate approvals from each Member State.

Figure 1: EU Centralized Drug Approval Procedure





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As shown in figure 1, once the EMEA ensures that the application is complete, the CPMP selects two of its members—known as rapporteurs—to perform independent scientific evaluations of the safety, efficacy, and quality of an application.<sup>11</sup> The rapporteurs can draw on two sources of EU-wide scientific expertise in forming their review teams—experts from the national marketing authorities of Member States and any of the 1,200 outside experts located at universities and institutes throughout Europe.<sup>12</sup>

Once the rapporteurs have completed their respective evaluations, they present the results to the CPMP, which then renders an opinion. The CPMP must render its opinion within 210 days after the application was submitted.<sup>13,14</sup> If a CPMP opinion is favorable, it is transmitted to the applicant, all Member States, and the Commission. The Commission uses the CPMP's opinion to prepare a draft decision. If the Member States raise important new scientific or technical questions, the Commission may refer the case back to the CPMP for further consideration. At this point in the approval process, Member States may object to the decision only if they believe the product poses a significant risk to public health in their country. If no objections are raised by the Member States, the Commission's draft decision is submitted to its Standing Committee on Medicinal Products for Human Use. The Standing Committee either agrees with the Commission's decision or, if there is no qualified majority,<sup>15</sup> refers the decision to the Council of Ministers for consideration.<sup>16</sup> Upon request, the EMEA will inform any concerned parties about the final decision, and the public is notified when a marketing authorization is granted through publication in the Official Journal of the European Communities.<sup>17</sup>

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<sup>11</sup>The CPMP may also arrange tests to verify a manufacturer's control methods described in the application or inspect the manufacturing site.

<sup>12</sup>As of December 1995, the national marketing authorities were estimated to have approximately 1,250 staff available for the review of human pharmaceutical products.

<sup>13</sup>The clock can be temporarily stopped if the reviewers request additional information from the applicant.

<sup>14</sup>In cases in which the CPMP cannot reach consensus, the opinion becomes the majority view; divergent opinions may be recorded in the formal record of the opinion.

<sup>15</sup>The Standing Committee includes representatives from all 15 Member States. The number of votes each Member State has depends on its population. Thus, the Member States with larger populations, such as Germany, France, Italy, and the United Kingdom, have more votes than the less populated Member States and therefore have greater influence over the decisions about new drug applications. The Standing Committee currently has a total of 87 votes, 62 of which constitute a qualified majority.

<sup>16</sup>The Council of Ministers is composed of representatives from all the Member States. The Council analyzes Commission proposals and enacts EU-wide legislation.

<sup>17</sup>A marketing authorization license is valid for 5 years and renewable for 5-year periods after consideration by the EMEA.

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If, on the other hand, the CPMP renders an unfavorable opinion, the applicant may appeal the decision to the EMEA. During the appeal process, the CPMP may obtain the views of additional experts who were not involved in the first consideration of the application. The CPMP's final opinion is processed in essentially the same manner as a favorable opinion; that is, the final decision is made by the Commission or Council of Ministers. The centralized procedure is expected to take between 298 and 448 days depending on whether the applicant appeals an unfavorable CPMP opinion, the Member States raise important new scientific or technical questions, or the Standing Committee cannot reach consensus on a Commission draft decision and refers the matter to the Council of Ministers.

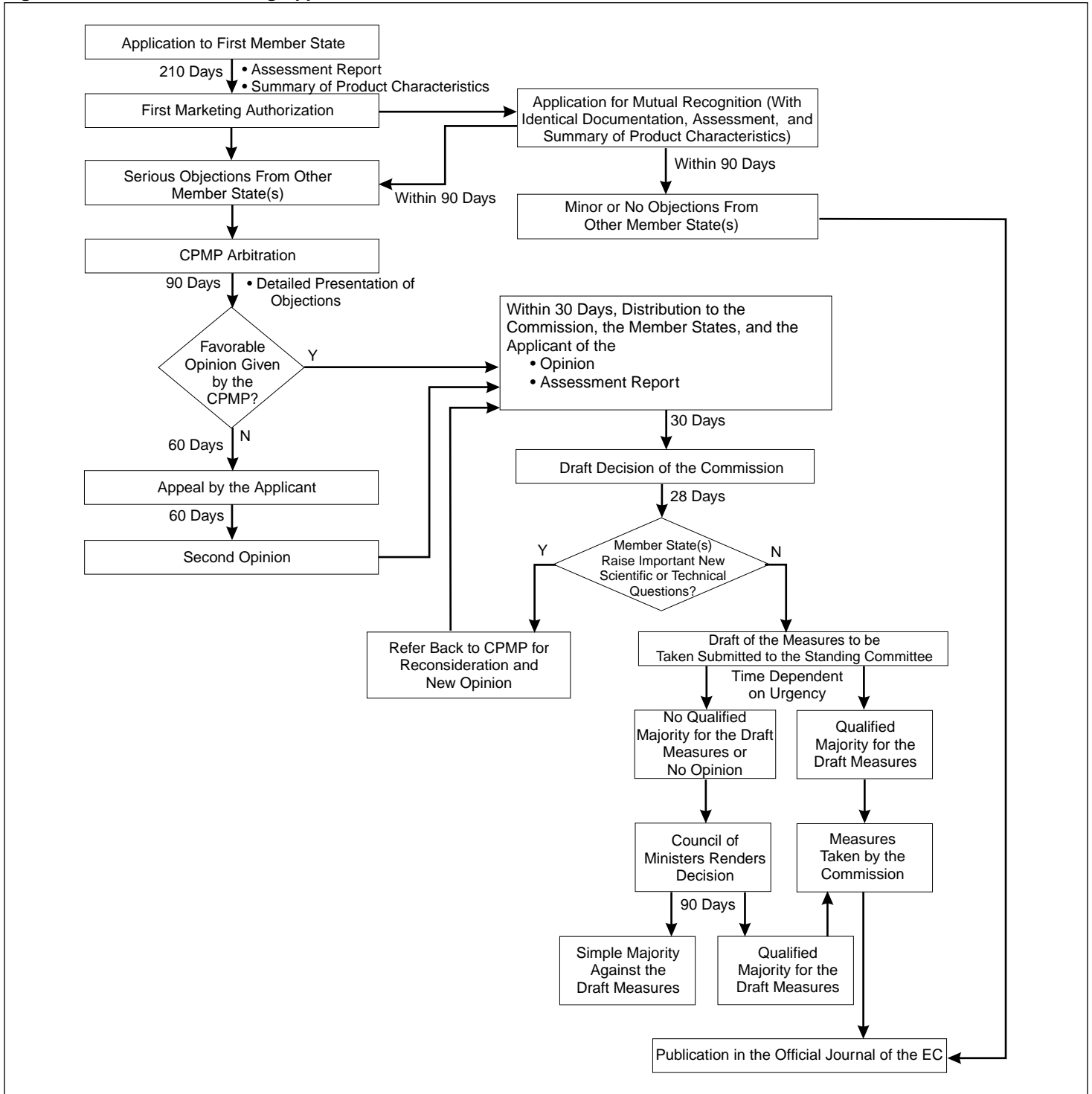
According to an EMEA official, as of December 1995, almost 1 year after the EMEA had become operational, pharmaceutical companies had filed or intended to file 30 new applications under the centralized procedure, and 20 had started the evaluation process. In addition, the EMEA had received 18 applications submitted under the former concertation process. The CPMP has given positive opinions on 8 of these 18 applications, and the Commission has granted EU marketing authorizations for three of those opinions.

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## The Decentralized Procedure

For optional innovative products, pharmaceutical companies can either use the EMEA's centralized procedure or follow a decentralized procedure to obtain mutual recognition of a new drug by the EU Member States. Under the decentralized procedure (see fig. 2) an applicant can go directly to a national marketing authority to obtain permission to market its product in that Member State and then seek to have other Member States accept the marketing approval of the first Member State.

Figure 2: EU Decentralized Drug Approval Procedure



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Once an application has been submitted, a Member State's national marketing authority has 210 days to decide whether or not to grant an authorization to market the product in the Member State.<sup>18</sup> If a Member State grants a marketing authorization, the applicant may seek to have one or more other Member State(s) where the applicant wishes to market its product recognize the authorization of the first Member State. Within 90 days of receiving the application, the other Member State(s) must decide whether to recognize the approval.

If the other Member State(s) recognize the marketing authorization of the first Member State, an applicant may market its product in each Member State. If the other Member State(s) raise objections to mutual recognition that cannot be resolved within 90 days, the case is referred to the CPMP for arbitration. Once the CPMP gets involved in the process, the steps are the same as those followed for the centralized procedure. CPMP opinions under the decentralized procedure, once accepted by the Commission, are binding on all the Member States.

The decentralized approval procedure is expected to take between 300 and 686 days depending on whether other Member States object to the marketing authorization granted by the first Member State, objections lead to a formal arbitration by the CPMP, the applicant appeals an unfavorable opinion, the Member States raise important new scientific or technical questions, or the Standing Committee cannot reach consensus on a Commission draft decision and refers the matter to the Council of Ministers. According to an EMEA official, as of December 1995, the EMEA had not been involved in any arbitration proceedings relating to disputes among the Member States under the decentralized procedure.

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## Industry Concerns

Pharmaceutical industry officials acknowledge that filing NDAs under the centralized procedure will allow a company to market its product(s) in all Member States within a relatively short period of time at approximately 60 percent of the cost of obtaining 15 individual marketing authorizations. However, some officials said they are hesitant to use the centralized procedure in the short term to obtain approval for nonbiotechnology pharmaceutical products for several reasons.

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<sup>18</sup>Member States that receive an application for licensing a product that is already being assessed in another Member State may proceed with an independent assessment or suspend their assessment until the other Member State has decided to grant or refuse the license. If a Member State suspends its assessment, it must so inform the applicant and the other Member State.

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First, under the centralized procedure, a company has less influence over which rapporteurs will review its application than it does under the decentralized procedure. While a company can request particular rapporteurs, the CPMP will ultimately make the selection.<sup>19</sup> According to industry officials, firms want their preferred rapporteurs because of the significant time and resources they have invested in establishing relationships with certain national marketing authorities, particularly in countries with large pharmaceutical markets. Under the centralized procedure, drug sponsors are concerned that the EMEA may assign an innovative product to a less experienced rapporteur who cannot adequately review or convincingly support the product before the full CPMP.

Regulatory and industry officials believe that this concern will be somewhat mitigated by the new procedures' use of two rapporteurs. They expect that using two rapporteurs, rather than the one used under earlier procedures, will improve the quality of the drug approval process in several ways. First, by working independently, the two rapporteurs—and the teams they assemble—should uncover most concerns that might be raised at a meeting of the full CPMP. Second, being a rapporteur for an NDA carries great prestige, and the CPMP and Member States will place pressure on the review teams to prepare a thorough evaluation. Third, rapporteurs will have access to the scientific expertise available across the EU.

Moreover, according to an EMEA official, the CPMP does consider drug sponsor preferences in its selection of rapporteurs. In 1995, the CPMP was able to give drug sponsors one of their rapporteur choices in every case. However, the CPMP recognizes that this may not always be possible in the future. Under the centralized procedure, in 1995, representatives from all of the Member States except Greece were chosen as rapporteurs or corapporteurs for at least two applications. The United Kingdom was selected as a rapporteur or corapporteur most often (nine times) with members from France and Germany involved in eight and seven applications, respectively.

A second concern voiced by industry and regulatory officials is that the new procedures will function as intended only if members of the CPMP and the Standing Committee, who are appointed by their Member States on the basis of their scientific or regulatory expertise, are able to look beyond

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<sup>19</sup>According to industry officials, companies prefer rapporteurs who are willing to interact with them throughout the drug development and approval processes, are knowledgeable about a firm's clinical trial procedures and products, have an open review process, share a common language, and have a proven track record in approving pharmaceutical products quickly.

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their national identity to represent EU-wide interests. The members of these committees have to accept an EU-based approval process and EU-based decisions in order for the new procedures to successfully expedite the drug approval process. According to a senior EMEA official, the EMEA is doing all that it can to encourage the CPMP members to act in the best interests of the EU, regardless of their national identities. However, the EMEA official acknowledged that it will take time before the members feel comfortable with one another and the new procedures.

Finally, pharmaceutical industry officials told us that, in the short term, industry will monitor progress with the centralized procedure and may delay using it for nonbiotechnology product approvals until the EMEA can establish a track record for drug approvals. Industry likes the multiple approval options for pharmaceutical products because they create competition among the national marketing authorities and the EMEA, encouraging them to be more efficient. Further, these options allow firms to pursue different marketing strategies for their various pharmaceutical products.

During the EMEA's first year of operation, however, there were indications that industry was using the centralized procedure for optional nonbiotechnology products. According to EMEA status reports, two-thirds of the 30 new centralized applications that industry filed or intended to file could have been filed using the decentralized procedure. Nevertheless, industry officials contend that future prospects for using the centralized procedure are dependent on the EMEA's success in expediting the drug approval process.

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## EMEA Tasks, Structure, Staffing, and Financing

The EMEA was created by the Commission in 1993 to administer the new centralized approval procedure, which is mandatory for biotechnology and optional for other high-technology and innovative pharmaceutical products.<sup>20</sup> The EMEA also arbitrates disputes under the new decentralized procedure in order to achieve mutual recognition of Member State approvals for most other medicines.<sup>21</sup> The EMEA is funded by the Commission and industry application fees and has a small permanent staff and two scientific committees that draw upon EU-wide scientific expertise.

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<sup>20</sup>The EMEA did not become operational until February 1, 1995, after administrative and logistical issues had been resolved.

<sup>21</sup>The EMEA's CPMP also reviews products of EU-wide interest, such as treatments for AIDS, and products identified through pharmacovigilance alerts.

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## EMEA Tasks

The EMEA provides administrative, technical, and scientific support for both drug approval decisions under the centralized procedure and disputed decisions under the decentralized procedure. Under the centralized procedure, the EMEA is responsible for coordinating the evaluation of the safety, efficacy, and quality of human pharmaceutical products that will be marketed throughout the EU. Through its scientific committee, the CPMP, the EMEA also evaluates assessment reports, summaries of product characteristics, labels, and package inserts for pharmaceutical products. Finally, the EMEA provides advice to drug sponsors on issues relating to the conduct of tests and trials necessary to demonstrate the safety, efficacy, and quality of pharmaceutical products. In 1995, the CPMP received 20 requests for scientific advice from pharmaceutical companies. According to EMEA and industry officials, this interaction between the industry and the EMEA is beneficial to the European pharmaceutical industry because it increases the industry's interaction with the European reviewers of its product applications.

In addition to coordinating the assessment of new drug applications and resolving Member State disputes, the EMEA is responsible for monitoring adverse drug reactions, an activity known as pharmacovigilance.<sup>22</sup> The EMEA also ensures that the public receives timely and accurate information about the safe and effective use of these products. While national pharmacovigilance systems have existed for some time in the EU, the requirements and structure of those systems have varied considerably. According to a recent report, these differences have made compliance with all the regulatory requirements difficult for multinational pharmaceutical companies, thereby endangering patients who may not have received standard safety information about a particular product.<sup>23</sup>

The new EU regulations are intended to strengthen and coordinate existing pharmacovigilance systems. As part of the new system, the EMEA is responsible for creating a data-processing network for the rapid transmission of information among the national marketing authorities in the event of a pharmacovigilance alert.<sup>24</sup> The EMEA is also responsible for

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<sup>22</sup>Pharmacovigilance involves collecting information on adverse drug reactions at pre- and postmarketing stages, scientifically evaluating these reports, and taking whatever regulatory actions may be appropriate following the analysis of the reports.

<sup>23</sup>Developments in International Pharmaceutical Regulation: Implications for the United States, pp. 5-1, 5-2.

<sup>24</sup>In 1995, the Commission requested bids on a \$2 million feasibility study to determine how to establish an information network on adverse drug reactions and what resources would be necessary to fund such a network. The European Community Joint Research Center in Ispra, Italy, was selected to conduct the study.

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formulating, as necessary, opinions on measures to ensure the safe and effective use of such pharmaceutical products.

The EMEA also performs several other functions. It coordinates Commission and Member States' responsibilities for verifying industry compliance with good manufacturing, laboratory, and clinical practices. It also provides technical assistance for maintaining a database on pharmaceutical products for public use and assists the Commission and Member States in providing information about pharmaceutical products to the public. In addition, the EMEA is in the process of developing ways to electronically transmit data between its administrative arm, the secretariat, and the national marketing authorities to track the flow of information during the review process.<sup>25</sup> The EMEA also translates all documents into the 11 languages used in the Member States. Finally, the EMEA promotes technical cooperation among the Commission, Member States, international organizations, and other countries regarding the evaluation of pharmaceutical products.

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## EMEA Structure and Staffing

The EMEA is composed of a Management Board, two scientific committees, and a permanent secretariat. The Management Board is the EMEA's governing body and is responsible for budgetary and resource matters. It consists of two representatives each from the European Commission, the European Parliament, and the Member States, for a total of 34 members.

The scientific committees, the CPMP and the CVMP, each consist of 30 members—two from each Member State—who are primarily responsible for acting as rapporteurs to coordinate the review of NDAs. The rapporteurs have access to the staffs of national marketing authorities in other Member States, as well as to any of the 1,200 outside experts on the EMEA's European experts list.

By the end of 1995, the permanent secretariat consisted of about 67 staff but was expected to grow to 250 staff by the year 2000. The secretariat is charged with providing general administrative and logistical support to the scientific committees, as well as administering the day-to-day activities of the EMEA. The permanent secretariat consists of four units:

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<sup>25</sup>According to an EMEA official, a prototype Automated Tracking System is undergoing testing at the EMEA. The information from the system will be available only to those inside the evaluation and decision-making process.



- the Administration and Logistical Unit, which is responsible for personnel, administration, budget, accounting, and organization of and interpretation for conferences and meetings;
- the Human Medicines Evaluation Unit, whose two sections support the centralized and decentralized procedures for approval of pharmaceutical products for human use;
- the Veterinary Medicines Evaluation Unit, which supports centralized and decentralized procedures for approval of pharmaceutical products for veterinary use and monitors the maximum residue levels in foodstuffs of animal origin; and
- the Technical Coordination Unit, which is responsible for inspection, pharmacovigilance, and technical documentation activities.

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## EMEA Financing

Initially, the EMEA was expected to be financed equally by industry application fees and Commission funds. However, the EMEA reported that about one-third of its funding for 1995 actually came from industry fees, while about two-thirds came from the Commission. The EMEA's budget for 1995 was approximately \$17 million.<sup>26</sup>

The application fee for authorizing a pharmaceutical product for human use under the centralized procedure ranges from about \$165,200 to approximately \$236,000, depending on how many different product strengths and forms, such as tablet or liquid, are being considered. The EMEA receives half of the fees to support its operations, and the other half are split between the two review teams formed by the designated rapporteurs. Other fees, which are detailed in Commission regulations, are charged to process application variations, extensions, and renewals; inspect manufacturers' facilities; and arbitrate Member State disputes.

According to industry and regulatory officials, the Member States differ in how they would like to see the EMEA funded. Some of the Member States, particularly the United Kingdom, would like the EMEA to be fully financed by industry fees. Other Member States have resisted a total fee-based financing scheme because they view industry support of a public health agency as a conflict of interest. Consequently, they want the Commission to maintain oversight responsibility of the EMEA through its funding mechanism. The Member States and Commission agree that the EMEA's financing should be reviewed in about 3 years, with the objective of increasing the proportion of the budget financed by the industry. However, according to a senior Commission official, the Commission is likely to

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<sup>26</sup>Throughout this section, we use an exchange rate of \$1.18 U.S. dollars per European Currency Unit.

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retain its oversight control by funding at least 20 percent of the EMEA budget in the future.

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## Agency Comments

We obtained comments on a draft of this report from the EMEA, FDA, representatives of the European-based pharmaceutical industry, and experts in international drug regulatory policies. In general, they found the report to be accurate and complete and provided specific technical comments, which we incorporated into the report where appropriate.

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This report was prepared by John C. Hansen, Assistant Director; Thomas J. Laetz; and Mary W. Freeman. Please call Mr. Hansen at (202) 512-7105 if you or your staff have any questions about this report.

Sincerely yours,



Sarah F. Jaggar  
Director, Health Financing and  
Public Health Issues

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## Abbreviations

CPMP	Committee for Proprietary Medicinal Products
CVMP	Committee for Veterinary Medicinal Products
EMA	European Medicines Evaluation Agency
EU	European Union
FDA	Food and Drug Administration
NDA	new drug application

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# Glossary

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<b>Commission of the European Communities</b>	The central regulatory body in the EU that (1) drafts legislation in the form of directives and regulations designed to foster a single market in Europe and (2) enforces EU rules. The Commission also prepares draft decisions, on the basis of CPMP opinions, on the licensing of pharmaceutical products.
<b>Committee for Proprietary Medicinal Products (CPMP)</b>	Committee within the EMEA, composed of two representatives from each Member State, that renders scientific opinions about the safety, efficacy, and quality of new pharmaceutical products. The CPMP also has a role in pharmacovigilance issues, developing guidelines, giving scientific advice to companies developing pharmaceutical products, and providing quality information to health professionals and patients.
<b>Council of Ministers</b>	European Council composed of representatives from all the Member States. The Council analyzes Commission proposals and enacts EU-wide legislation.
<b>European Medicines Evaluation Agency (EMA)</b>	Central agency within the EU that supports the CPMP in its scientific evaluations of pharmaceutical products. The EMA also verifies compliance with EU good clinical practices and good manufacturing practices and provides technical support to the Member States' national marketing authorities.
<b>European Union (EU)</b>	Formerly known as the European Community, the EU was established by treaty to create a single market. The EU currently consists of 15 countries commonly referred to as Member States. The 15 Member States are Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the United Kingdom.
<b>National Marketing Authority</b>	The regulatory authority in each Member State that is responsible for the approval of new human and veterinary pharmaceutical products in that Member State. National marketing authorities also inspect manufacturing facilities, monitor quality control, and perform pharmacovigilance activities. The size and structure of each national marketing authority vary among Member States.

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**Pharmacovigilance**

The process of collecting information on adverse drug reactions at the pre- and postmarketing stages, scientifically evaluating these adverse drug reaction reports, and making the regulatory decisions that result from this analysis.

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**Rapporteur**

A CPMP member selected to lead the scientific evaluation of a new drug application and discuss its merits and shortcomings before the CPMP.

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**Standing Committee on Medicinal Products for Human Use**

Committee within the Commission, comprising representatives from all 15 Member States, that is responsible for approving draft licensing decisions for pharmaceutical products on the basis of the Commission's draft decisions.

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**Summary of Product Characteristics**

The EU's version of the full prescribing information for a product that is supplied to physicians separately from the product.

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