Policy Making on Data Exclusivity in the European Union: From Industrial Interests to Legal Realities

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Abstract After lengthening the duration of patents to twenty years in 1984, the pharmaceutical industry has turned to data exclusivity as a major vehicle for extending market protection, even after patents expire. Such protections give companies the power to tax consumers for innovation by charging above-market prices. This article draws upon unique information to describe how key actors lengthened data exclusivity for patented drugs to postpone generic competition in the European Union (EU) just before ten new members joined it. We explore the political route and the interests of different actors to understand the process by which industrial interests are translated into legal realities in the world's largest harmonized market. Several factors influenced the outcome, including the role of the pharmaceutical unit of the Directorate General for Enterprise of the European Commission in promoting the interests of the innovative branch of the industry, the time pressure to find a viable compromise before EU enlargement, and the heterogeneous preferences of the other actors. The case illustrates the inherent tension between the desire of both health care administrators and patients for high-quality, low-cost medicines and the objective of the innovator pharmaceutical industry to find and approve new drugs that are price protected and sell them in a way that maximizes revenues.

Introduction

Since Adam Smith, competition has been recognized as the principal engine of innovation. While most competitors sweat out the market pressures, the more innovative ones come up with a new feature or convenience that leads customers to choose it over others. To this basic reality was added patent protection. If society gave inventors a temporary stay

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from head-to-head competition in return for sharing their discoveries rather than keeping them secret, others could build on these inventions and accelerate innovation while the inventors could use the exemption time to sell their ideas and profit from all their hard work. A crucial feature is that this protection comes to an end so that competitive forces spur companies to innovate again.

In the debate over pharmaceutical intellectual property rights, data exclusivity has become another, more recent and significant form of protection. Essentially, data exclusivity for a specified period prohibits a regulatory authority from affirming the safety of a bioequivalent generic by using the preclinical and clinical trials data submitted when a product was initially registered. Central to this approach is the idea that the initial sponsoring company paid for the trials and thus owns the data, though the trials were done for a public authority and for a public purpose.

Whereas patents are granted to innovations of pharmaceutical products, data exclusivity is based on a different trade-off, "demanding that pharmaceutical companies provide data on safety and efficacy of a new medicine in exchange for treating these data as a trade secret for a limited period" (Pugatch 2006: 100). The provisions on data exclusivity overlap with and complement patent protection and may extend beyond it. Pharmaceutical products can thus be protected against generic competition in two ways: through patents and through data exclusivity (Commission of the European Communities 2008).

Related to the discussion on patents and data exclusivity is regulation on prepatent-expiry development and testing of generic drugs. Manufacturers of generic drugs may use the patented invention to obtain marketing approval — for example, from public health authorities — without the patent owner's permission and before the patent protection expires. The underlying logic of a so-called Bolar provision is that it reduces delays in the launch of a generic product, because the generics industry is entitled to conduct the necessary bioequivalence and quality manufacturing studies while the reference product is still under patent protection.

In the United States, the 1984 Drug Price Competition and Patent Term Restoration Act granted a five-year period of data exclusivity to new drugs and three years for new indications of an existing medicine. In Europe, data exclusivity has been a European Community affair since 1987, when a period of six or ten years of data exclusivity for new drugs was introduced (Council of the European Communities 1987a). In 2001 the Directorate General for Enterprise (DG Enterprise), the commerce department of the European Commission, submitted a proposal for harmonization

of national differences in data exclusivity extending up to ten years plus an additional year for new therapeutic indications as part of the pharmaceutical review. During negotiations, the "Eurogenerics" and "historical reference principle" were also introduced, respectively allowing national authorities to use the data of (pre)clinical trials of an originator product present in another member state and allowing companies to develop generics of original medicines that had *previously* been on the market. In addition, a Bolar provision was suggested (Commission of the European Communities 2001a).[1]

The ten accession countries[2] that were about to enter the European Union provided shorter data protection periods or none at all. We will analyze what in the end triggered the adoption of such a lengthy period compared with the American counterpart and despite reluctance of these new member states. Why did the Commission introduce a proposal for the world's longest data exclusivity period? Why did member states agree, given that the extended exclusivity period could delay generic competition and therefore increase national health care spending on pharmaceuticals? Why was the European Parliament (EP) in the end willing to compromise? And what was the role of the generics and the innovative branch of the industry in this political game?

This is an in-depth case study of how the research-based pharmaceutical industry has tried and succeeded in promoting its interest in maximizing protection in the context of two transcendent issues. The first of these issues is the inherent tension that exists between, on the one hand, health care systems and patients and their need to access good medicines at affordable prices and, on the other hand, the innovator pharmaceutical industry and its objective to find and approve new drugs that are price protected and then sell them to maximize revenues. The second issue is how, in federated governments such as the European Union and the United States, to reconcile the desire of member states to retain control over their services with the desire of the overarching government to provide uniform and integrated regulations that support integrated markets.

1. The review concerned Council Regulation 2309/93/EEC Laying Down Community Procedures for the Authorization and Supervision of Medicinal Products for Human and Veterinary Use and Establishing a European Agency for the Evaluation of Medicinal Products (Council of the European Communities 1993) and Directive 2001/83/EC of the European Parliament and the Council of the European Union on the Community Code Relating to Medicinal Products for Human Use (European Parliament and Council 2001). The regulatory framework of the so-called Community code concerns licensing, manufacturing and importing, labeling/packaging requirements, wholesale distribution, advertising rules, and pharmacovigilance.

2. The accession countries that would become EU member states as of May 2004 were Poland, Malta, Slovenia, Slovakia, Cyprus, Hungary, the Czech Republic, Latvia, Estonia, and Lithuania.

This article analyzes the events based on extensive literature review and document analysis (e.g., EU documents such as Commission communications and European Parliament minutes, as well as publications from the press agency *Agence Europe*; *Scrip*, the main international trade press of the pharmaceutical industry; and *Revue Prescrire*, a French drug bulletin). In addition, a series of in-depth interviews with key actors were held during 2006–2007 (see appendix A). After outlining the analytical framework, this article sketches the economic significance of data exclusivity and its broader consequences, after which it analyzes the dynamics of the policy process in detail. As we show in our discussion, data exclusivity is only one of the ways to delay generic price competition.

Analytical Framework: Actors, Preferences, and Institutions

The starting point of this policy analysis is that institutions—defined as the set of formal and informal rules of the game that structure the course of action that actors may choose—influence policy making (Scharpf 1997: 38). They constrain or facilitate strategic action but do not determine actor behavior. In other words, institutions only create a set of strategic options for actors, but how they use these options depends upon their preferences and their assessment of the consequences of acting on the strategic options available. In fact, one may conceptualize the use of institutions as a strategic game in itself.

From a problem-solving perspective, institutions are important. They have a strong impact on whether agreements can be reached and therefore on the problem-solving capacity of an institutional setting. At the heart of EU policy making, several rules regulate the interplay between the European Commission, the EP, and the Council. (For a detailed description of the functioning of the EU, see Nugent 2003; Peterson and Bomberg 1999). All deliberations start with a Commission proposal, which gives the Commission an important agenda-setting role. A proposal is prepared by the responsible Directorate General (DG), often with outside assistance from consultants at both national and sectoral levels as well as horizontal coordination with other DGs.

Negotiations on data exclusivity took place under the codecision procedure (see appendix B). The most important feature of this procedure is that it provides for joint decision making and direct negotiations between the Council and the EP and makes it possible for the EP to reject draft legislation. The EP has a strong committee structure. It is within the commit-

tee that most amendments are proposed and the Council common position is scrutinized. A key player in this process is the rapporteur.

In the EP's first reading, the Commission's legislative proposal is being considered. A simple majority of all members present is necessary for amendments. The European Commission will incorporate amendments that it considers an improvement of the initial proposal or that most likely will facilitate agreement.

After this first reading, there are three possible scenarios. First, the law can be adopted if the Council accepts the Commission proposal that has also been accepted by the EP during its first reading without any amendments. Second, the law can also be adopted if both the Commission and the Council accept all EP amendments. In all other situations, the Council adopts a common position, generally based on both internal compromises and the EP's amendments.

To amend or reject the Council's common position in the second reading, an absolute majority (i.e., half of all members plus one) is required in the EP. In a situation where the Council cannot accept second reading amendments, both actors try to negotiate an agreement in a conciliation meeting. Given the complexity of conciliation meetings, where up to one hundred people can be in the room, an informal trialogue in a smaller setting often replaces the formal conciliation committee. To foster agreement, this informal trialogue may even be initiated before the formal second reading of the EP.

One can conceptualize the voting rule in the Council as another important institution. If agreement between the member states is difficult, the rule of unanimity is likely to block the policy-making process, because each country has a veto position. The qualified majority voting (QMV) rule in the Council, a weighted decision rule that allocates a certain number of votes to each member state, implies that an opposing minority can be overruled by a majority in favor of a policy proposal.[3]

Generally, EU governments search for consensus and try to avoid decisions that violate the vital interests of a member state (Scharpf 2006: 849). However, in case of a policy conflict—either because of a loss of benefits, a loss of decisional power, or the costs of instrumental adjustments

3. Overall, smaller member states are overrepresented. Before the 2004 enlargement, Germany, France, Italy, and the United Kingdom had 10 votes; Spain, 8; the Netherlands, Greece, Belgium, and Portugal, 5; Sweden and Austria, 4; Denmark, Finland, and Ireland, 3; and Luxembourg, 2. A qualified majority needed 62 votes cast and a blocking minority 26 votes. The minimum number of countries that could form a qualified majority was eight (71.26 percent), whereas a minimum number of three countries could form a blocking minority.

(Héritier 1999: 15)—a deadlock may occur. The Commission attempts to circumvent such a political impasse through various escape routes, in effect, "policy strategies and patterns that 'make Europe work' against the odds of the given institutional conditions and the enormous diversity of interests" (Héritier 1999: 1).

The major actors directly or indirectly involved in the process for data exclusivity are the EU and national authorities, including responsible ministries and agencies, the pharmaceutical industry, and patient/consumer organizations affected by the legislation (see Feick 2005).

In this article, we analyze how the institutional structure affected the political controversy on data exclusivity. We focus upon the right of initiative and the Commission's role as mediator, the codecision procedure and the informal trialogue, and the QMV rule in the Council. Before sketching the dynamics of negotiating in the fourth section ("From Industrial Interests to Legal Realities"), we first explain the global importance of data exclusivity in the next section.

The Global Significance of Data Exclusivity

Economic Significance of Data Exclusivity

The central justification for data exclusivity is that, as with patents, the longer an innovator company enjoys protection from price competition (i.e., market exclusivity), the greater its incentive to innovate. This is confirmed by Grabowski (2007), who claims that "without a data exclusivity period, there would be little incentive to invest in developing and marketing new product candidates with few remaining years of patent protection or with uncertain forms of protection" (Grabowski 2007: 3). The related argument is that research and development (R&D) is a high-risk and costly process. But the cost is inversely related to risk, and most of the cost occurs in later trials, when risk is low and time to market is shortest. A key bar graph (Grabowski 2007: 33) shows that the mean length of trials has increased from thirty-two to ninety-eight months over the last twenty years, but it is based on proprietary, unverifiable data from the industry's principal policy research center and differs from public, verifiable data submitted by companies that show trial lengths have not increased and average sixty-one months (Keyhani, Diener-West, and Powe 2006). Moreover, there is no academic consensus about accurate costs. Whereas Grabowski cites his own research to claim that R&D costs on average US$1.3 billion per new drug, data from National Institutes of Health and from the Food and Drug

Administration and audited tax returns indicate that the median net costs are closer to one-tenth of this amount (Light 2007; Light and Warburton 2005).

Although only a few pharmaceuticals benefit from the extra protection of data exclusivity beyond patent expiry (Pugatch 2004), it provides backstop protection in cases where patents are not sufficient. The option to extend the privileged time of market exclusivity (Angell 2005: 173–174) via data exclusivity explains the strong pressure by the research-based pharmaceutical industry on legislators to extend data exclusivity periods. Furthermore, disputes and litigation in respect to data exclusivity are initiated by innovator companies as a deliberate strategy to delay market access of generics. Even though the chances of winning in court are low, litigation may effectively delay market entry of generics by creating a maximum level of legal uncertainty (Commission of the European Communities 2008: 269).[4]

In addition to these litigation strategies, there are several situations in which data exclusivity may result in a delay of price competition from generics. The first possibility is when patents provide little or no protection. Sometimes a company does not own the patent rights or they expired because a medicine was discovered long ago. The most celebrated drug for which data exclusivity provided the key market protection is the unpatented anticancer drug Taxol, discovered by the U.S. National Cancer Institute in 1962 and marketed by Bristol-Myers Squibb in 1994.[5]

A second possibility occurs when the effective patent life (i.e., patent period after marketing authorization) is shorter than the data exclusivity period. Even though "very few high-selling drugs gain further marketing monopoly from the provision afforded by data exclusivity" (IMS Health 2001), this may occur when the R&D process of a drug takes an exceptionally long time.

A third circumstance occurs with the narrow scope of patent claims often given to biological pharmaceuticals, so that data exclusivity will play a pivotal role. Biologics include such substances as vaccines, cells, blood, and viruses. Given the complexity of these products, generic duplication

4. Marketing authorizations were delayed by four months on average in cases where the research-based industry interfered in administrative proceedings of generics companies. These interventions included both patent-related issues as well as cases concerning data exclusivity (Commission of the European Communities 2008:294).

5. As James P. Love stated in the context of discussing Taxol's market protections, "When drugs are not protected by patent, it is because the company does not own the rights to the discovery of the drug, or the key inventions relating to uses of the drug" (1997).

is not a straightforward process. Thus far, it remains unclear whether a generic competitor can refer to the registration files of the originator biologic for a marketing authorization after the patent expires or whether it has to gather additional data.

In theory, the marketing of a generic may only be blocked if there is a valid patent. No company is prevented from generating its own test data (Pugatch 2006: 100). However, in practice, apart from ethical considerations of replicating tests on animals and human subjects, the financial resources required for clinical testing create a too high barrier for most generics companies (Sanjuan Rius 2006). Therefore, data exclusivity is increasingly important as another strategy for delaying generic price competition (Pugatch 2006), affecting both the research-based and the generics industry.

Industry representatives and politicians emphasized the need for Europe to have a longer data exclusivity period than the United States as part of its struggle to gain an edge and win back research investments that the industry has shifted to the United States. However, whether or not the EU has strong data exclusivity provisions does not matter in a global market for pharmaceuticals. American-based companies fall under the same regime as European-based companies when applying for a marketing authorization through the European Medical Agency; thus, they both benefit from the European rules on data exclusivity. Therefore, promoting the growth of the European research-based pharmaceutical industry as part of a larger effort to make Europe more attractive to R&D than the United States has nothing to do with data exclusivity as such.

Broader Consequences of Data Exclusivity

In order to understand the broader consequences of the European discussion on data exclusivity, one has to understand how it differs from data protection. Article 39(3) of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) introduced the first international standard on data protection in 1995. It establishes broad parameters for national rules, allowing WTO members to apply different models for the protection of test data (for a juridical interpretation of article 39[3], see Correa 2006; Pugatch 2006; and Reichman 2006). WTO members are required to adopt measures to protect *undisclosed* test data submitted by pharmaceutical companies for market approval for a new chemical entity (NCE) against "unfair commercial use." Regulatory authorities are prevented from publishing or passing the data to third parties; however, TRIPS does not prohibit authorities from relying on test data for the approval of competing products, a practice that

falls outside the definition of unfair commercial use (Reichman 2006). Though the TRIPS agreement only provides minimum international standards on coverage (only NCEs), scope (data only protected against disclosure and not against reliance), and term of protection (no reference to a minimum period of protection), the research-based industry, together with several governments of industrialized countries, has claimed that investment in the development of (pre)clinical data can only be ensured by granting exclusive rights.

Following that it is common in the rest of the world for a product's patents not to be registered or recognized, data exclusivity serves as a broad barrier to manufacturing competing products at lower prices. This is why the industry has influenced the U.S. Department of Commerce to require developing countries in Central America, Africa, and Asia to agree to long periods for data exclusivity in its bilateral free trade agreements (Correa 2006; Light 2007), to prohibit trading partners from manufacturing, exporting, or importing cheap generics: "The new rules would far surpass the standard already established [for protecting IP rights of pharmaceutical companies] by the WTO's Agreement on TRIPS" (Health GAP 2003). Even though EU association agreements are more general on the issue of data exclusivity, countries are required to "grant and ensure adequate and effective protection of intellectual property rights in accordance with the highest international standards" (Commission of the European Communities 2004: 93).[6] There are also examples where the EU demanded the adoption of standards according to the latest exclusivity criteria (the "8 + 2 + 1" formula, discussed below), such as the Partnership and Cooperation Agreement (PCA) between the EU and Ukraine (Commission of the European Communities 2003).

The economic impact of data exclusivity on access to expensive vital drugs in developing countries greatly concerns Médecins sans Frontières (2003). According to an expert report for the Friends World Committee, the net effect of data exclusivity, independent of whether a medicine's patent is registered or has expired "is to create a web of restrictions and uncertainties that will have a powerful chilling effect on . . . the introduction of third-party (generic) medicines that are not under patent" (Abbott 2004). At issue are much lower prices and greater access for middle- and lower-income countries, because medicines often cost pennies per dose in volume to manufacture but have large up-front costs to develop.

Prior to the new pharmaceutical legislation, ten accession countries

6. The agreement between the European Community and the Republic of Chile, quoted here, is but one example.

had already made concessions to pharmaceutical interests by introducing EU legislation on supplementary protection certificates[7] and adapting their data exclusivity periods. Since most of them had provided shorter protection periods or none at all, they all opted for six years. However, after adoption of the law, they had to increase data exclusivity again. They expressed frustration at not having been formally included in the policy-making process (Eastern Europe Powers the EC Regulatory Convoy 2000), especially since the Commission had previously recognized that "the average per capita income in the countries of Central and Eastern Europe is considerably lower than the average in the current member states and raises therefore the question of how patients are to have access to affordable pharmaceuticals at prices which are realistic in the Single Market context" (Commission of the European Communities 1998: 9). In the next section, we will analyze how such a long period of data exclusivity was pushed through, despite opposition of the future EU member states.

From Industrial Interests to Legal Realities

Drawing on our in-depth interviews and archival analysis, we now turn to the heart of our study, exploring the dynamics of negotiation in order to understand the process by which industrial interests were translated into legal realities. The outcome of a policy-making process depends on actors' behavior (Scharpf 2000), which is influenced by the institutional structure and wider policy developments. We first outline the final outcome on data exclusivity and related issues. Next, after explaining the importance of the right of initiative and the brokering role of the European Commission, we focus on the impact of institutions on actors' behavior during policy making. Once the Commission brings its proposal forward, the codecision procedure includes both the Council and the EP; thus, we first analyze the role of the EP under codecision during its first and second reading and the informal trialogue.[8] Finally, we analyze the role of the Council under qualified majority voting (QMV) and the consensus norm.

7. In the EU, a supplementary protection certificate (SPC) is a sui generis extension of a patent introduced to compensate for the long time needed to obtain a marketing authorization. The SPC has a maximum duration of five years and comes into force when the corresponding patent expires. Thus it extends the effective patent life up to a maximum of fifteen years after a product has come onto the market.

8. The analysis presented in the subsections that follow is based on the role of various actors and will therefore not be fully chronologic. Between the first and the second reading of the EP, the Council negotiates a common position.

The Content of Data Exclusivity Regulation in the EU

Initially, data exclusivity was not an issue in Europe. When marketing authorizations were required for generics from 1975, no legal framework existed on data exclusivity (Sanjuan Rius 2006: 2). The Commission considered this problematic because unauthorized use of data "seriously penalizes the innovating firm which has had to meet the high cost of clinical trials and animal experiments, while its product can be copied at lower cost and sometimes within a very short period" (COM [84] 437 final, quoted in Dodds-Smith 2000: 96). In 1984, DG Enterprise of the European Commission therefore put forward a proposal for ten years of data exclusivity, after which a second applicant could cross-refer to the same data.[9] Subsequent negotiations resulted in Directive 87/21/EEC, which provided a period of six years of data exclusivity for most pharmaceuticals starting at the date of first market authorization, and ten years for biotechnological and high-technology medicinal products.[10] Member states were allowed to extend the period to ten years for all pharmaceuticals if they considered this "in the interest of public health" (Council of the European Communities 1987a: 36–37). Belgium, France, Germany, Italy, the Netherlands, Sweden, and the United Kingdom did so. Member states also had the option not to apply the six-year period beyond the date of patent expiry of the original product so that data exclusivity did not extend the twenty years of protection from free market competition. Denmark, Austria, Finland, Ireland, Luxembourg, Greece, Spain, and Portugal provided six years, with the latter three not offering data exclusivity beyond patent expiry (Kingham and Castle 2000: 214–215).

In 2001, DG Enterprise of the Commission put forward its proposal for harmonization of national differences in data exclusivity (see Commission of the European Communities 2001a), which finally resulted in the adoption of Directive 2004/27/EC in March 2004. (See table 1 for an overview of the different proposals suggested at different stages of the process.) The final compromise resulted in the so-called "8 + 2 + 1" formula on data exclusivity. This implies eight years of *data* exclusivity and two additional years of *market* exclusivity for authorizations (thus, generics companies could start the necessary tests after the expiration of the data exclusiv-

9. A different explanation for this proposal was that it should make up for the lack of patent protection for biotechnological products in Spain and Portugal, which were to join the Community in 1986 (Perry 2000).

10. For an overview of high-technology medicinal products, see the annex of Council Directive 87/22/EC (Council of the European Communities 1987b).

Table 1 Development of Data Exclusivity: Different Proposals at Different Stages

Content	Previous Legislation	Com1	ENVI 1	EP1	Com2	Common Position	ENVI 2	EP2	Final Agreement[a]
Period of data exclusivity concerning generics	6 or 10 yrs to be decided by each member state for reasons of public health / 10 yrs for CP	10 + 1 yrs	8 + 2 + 1 yrs	8 + 2 + 1 yrs	10 + 1 yrs	10 + 1 yrs for products obligatory using CP; 8 + 2 yrs for MRP/DP and products voluntary using CP	8 + 2 + 1 yrs	8 + 2 + 1 yrs	8 + 2 + 1 yrs
Data exclusivity for a new indication for a well-established substance	—	—	3 yrs	3 yrs	No	1 yr	3 yrs	1 yr	1 yr
Data exclusivity for wwitch from prescription to OTC status	—	—	3 yrs	3 yrs	2 yrs	1 yr	3 yrs	1 yr	1 yr

Table 1 (*continued*)

Content	Previous Legislation	Com1	ENVI 1	EP1	Com2	Common Position	ENVI 2	EP2	Final Agreement[a]
Bolar provision	—	Conducting tests and trials	Conducting tests and trials; application and granting MA	Conducting tests and trials; application and granting MA	Conducting tests and trials	Conducting tests and trials; consequential practical requirements	Conducting tests and trials; consequential practical requirements	Conducting tests and trials; consequential practical requirements	Conducting tests and trials; consequential practical requirements
Eurogenerics principle	—	—	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Historical preference principle	—	—	—	—	—	Yes	Yes	Yes	Yes

Source: based on Golub 1996

Notes: Com1 = Commission proposal; Com2 = revised Commission proposal; ENVI 1= European Parliament Environment Committee report 1; ENVI 2 = European Parliament Environment Committee report 2; EP1 = European Parliament first reading; EP2 = European Parliament second reading; OTC = over the counter; CP = centralized procedure; MRP = mutual recognition procedure; DP = decentralized procedure; MA = marketing authorization

[a]Vote against: Belgium

ity period of eight years), plus one additional year of protection for new indications of original products. As well, one year data exclusivity for new indications for well-established substances and one year data exclusivity for changes from prescriptive to over-the-counter (OTC) status. In addition, the final outcome includes a Bolar provision (which had been in place in the United States since 1984) as well as a Eurogenerics and historical reference principle.

In the remainder of this section, we will analyze how such a long period of data exclusivity was pushed through. We will analyze the strategic behavior of the most relevant actors within the given institutional structure and show that lobbyists for the innovative branch of the industry ("innovative industry," hereafter) won the battle before it began by limiting the scope of debate to variations of the same significant expansions.

The Commission's Right of Initiative

Regulation 2309/93 (Council of the European Communities 1993) required the Commission to evaluate the existing marketing authorization procedures and the functioning of the European Agency for the Evaluation of Medicinal Products (EMEA) by 1999. In 2000, Cameron McKenna and Andersen Consulting conducted this evaluation, taking into account the views of national authorities, industry, patients, and health care professionals. The report showed data exclusivity as one area justifying review, claiming that harmonization of national differences was necessary to develop a unified European market (CMS Cameron McKenna and Andersen Consulting 2000: 42). The huge package of legislative proposals — the so-called pharmaceutical review, with more than two hundred proposed changes and around six hundred parliamentary amendments — offered a good opportunity to lengthen data exclusivity. However, according to several interviewees, the evaluation hardly played a role: "The fact that some management consultancy firms say this, that, or the other — do I remotely think that this is an independent and necessarily honest point of view? No of course I do not. It is a game" (consumer lobbyist; see appendix A, item 14 [hereafter, A14]). In addition, according to an officer interviewed at DG Enterprise, the Commission started to develop its ideas long before the obligatory evaluation (DGE officer, A1). The Commission "knew what it was going to do and was drafting the legislation at the same time that Cameron McKenna was running around collecting information" (British civil servant, A6). Thus, several informants agreed that DG Enterprise had its own, long-term agenda to increase government protections from market competition through the data exclusivity route.

To support its proposal, the Commission funded a second report, titled "On Global Competitiveness in Pharmaceuticals: A European Perspective," which was drafted for DG Enterprise in 2000 (Gambardella, Orsenigo, and Pammolli 2000). According to this report, from the 1990s European industry had been losing competitiveness as compared to the United States, because of its patchwork quilt of regulatory and health care regimes, including pricing policies.[11] The Commission therefore emphasized the need to create some kind of incentive to "further improve existing medicinal products, in particular to develop new and important therapeutic indications. Such an incentive could be an additional data protection period" (Commission of the European Communities 2001b).

Aware that its proposal would cause controversy, the Commission's DG Enterprise presented it in terms of finding a balance between stimulating innovation and competition on generics. It therefore proposed a Bolar provision to promote competition. The Commission also had an interest in doing so. Before the review, several members of the EP (MEPs) had already asked for such a provision and, if not introduced by the Commission, the EP most likely would have put it forward. Furthermore, generics companies conducted their research before patent expiration in countries outside the Community where they were allowed to do so. A 1998 study on "policy relating to generic medicines in the OECD [Organisation for Economic Co-operation and Development]," conducted on behalf of the Commission, showed that, due to premarketing work done outside the EU, jobs might be permanently lost. In the extreme case, thirteen thousand jobs were at risk (National Economic Research Associates 1998). To address this problem, premarketing work had to be allowed in Europe as well. However, application for and granting of a marketing authorization, as such, did not have to be part of the Bolar provision.

The period of ten years of data exclusivity was not based on a calculation: "How do you distribute the costs which you have in early development, and all the failures of substances? In the end, it is not a mathematical decision; it is a political estimation of how much incentive for innovation you need" (DGE officer, A1). Yet such an estimation, or "finding a balance" between greater innovation by raising costs through protected prices and less innovation by reducing costs through open price competition, was done without data or evidence.

11. A new analysis of evidence to support this major policy claim finds little supporting data. European researchers continued to discover more major new drugs in the 1980s, 1990s, and up to 2003 (Stolk and Light 2008).

Agenda-Setting: Lobbying the Commission

The Commission's monopoly over what legal measures get reviewed meant that the industry was "quite naturally . . . keen to aid and abet the Commission, hoping thereby to promote its own points of view" (Danish civil servant, A3). For this second attempt at a ten-year exclusivity period, the European Federation of Pharmaceutical Industries and Associations (EFPIA) had already come up with a policy paper in 1999 (EFPIA 1999). A January 2000 letter from the European Generic Medicines Association (EGA) also referred to the ongoing dialogue: "There is serious discussion to harmonize all data exclusivity provisions at [the] national level. This is required for the proper function of the single market . . . . EFPIA is calling for ten years. We have called for five years and only covering new chemical entities. The Commission has floated the idea of seven to eight years and dropping the link to patents. However, the ten-year period for centralized products will remain as part of this plan" (Perry 2000). In the end, a proposal was adopted in line with what EFPIA requested.

In a reaction to the Commission proposal, EFPIA positioned itself as offering a reasonable balance between the needs of the industry, regulators, and patients, emphasizing the decreasing level of innovation and stressing the need to create a proper environment in the EU for innovative medicines (EC Reforms Balanced, Says Industry 2001). The EGA argued that the proposal did not constitute a real balance at all: the period of data exclusivity increased and the Commission failed to provide a real Bolar provision. Furthermore, the EGA claimed that "originator companies are requesting superfluous protection by means of data exclusivity for areas already protected" (EGA 2000). The EGA also questioned the causal link between data exclusivity and encouragement of innovation. Furthermore, the argument that clinical trials are very expensive and should therefore be protected was countered. According to the EGA, these trials are often cosubsidized by public bodies or research foundations. It would therefore be difficult to justify that these data solely belong to the company marketing the pharmaceutical. Beyond these arguments, the EGA framed the whole discussion as a choice between "public health versus private profit" (consultant, A4).

Greenwood (2003) described the Commission's relationship with the innovative industry as "clientilistic," with EFPIA making itself indispensable to the Commission through three or four experts on pharmaceutical regulation in DG Enterprise. A Dutch civil servant (A5) complained that "via a channel as DG Enterprise the limits of a democratic decision-

making system are reached. However, one can of course not totally blame this on the pharmaceutical industry; the Commission is guilty as well." Another observed that "the Commission is very much pro innovative industry, and the generics industry is considered the underdog" (Dutch civil servant, A7). There was constant contact between DG Enterprise and EFPIA. But according to a representative from DG Enterprise, this was completely normal: "Of course we have many direct contacts with the industry . . . . They are supposed to produce the medicines. They know best in the end" (DGE officer, A1). In this, as in many matters, there is a hierarchy of well-resourced expertise. At the top is an industry's trade association, richly funded and with skilled authorities on a topic, with ample time to help out in drafting legislation or the specifics of a regulation. Well below them are the three or four staff at the Commission who are responsible for drafting and knowing quite a bit about the area. Well below them are the key members of parliamentary committees who have many other things to do. They do not really have to understand the proposal in all its technical details. They are educated by the key Commission staff as well as industry-sponsored experts. This is one dynamic of regulatory capture, the economic theory that an industry will capture the regulatory process and exploit it to keep competitors out and protect its markets (Levine and Forrence 1990). Critics point out it makes matters worse that DG Enterprise is responsible for pharmaceutical policy rather than DG Sanco, the department of health (Garattini, Bertele, and Li Bassi 2003: 635).

Only after strong pressure to provide access to *all* stakeholders did the Commission organize a consultation in January 2001. However, important discussions had already taken place with industry: "In addition to the formal consultation process, the pharmaceutical industry was contacting the relevant people as early as possible" (EGA lobbyist, A12). Furthermore, one interviewee argued that the Commission's "consultation processes are essentially pretty cynical, and I think they almost inexorably lead to the conclusions that [the Commission] would find acceptable and that it wants to see" (consumer lobbyist, A14).

Whereas industry had good access to DG Enterprise, public health and consumer organizations were considered stakeholders of DG Sanco (see letter from Brunet to Health Action International in Medawar and Hardon 2004: 120). In addition, these organizations were not able to concentrate on the pharmaceutical review in total. For example, Health Action International (HAI) "is doing the best it can with painfully limited resources" and, given that data exclusivity "is really a quite sophisticated issue, . . .

you are not going to be able to get the press interested. . . . This is really for the generics industry to fight and we will hold their hand as much as we can, but you know this is not going to be our mainstream endeavor" (consumer lobbyist, A14). The situation was similar for the European Public Health Alliance (EPHA), which at the time had 3.5 full-time employees and "had to do the entire public health agenda" (PH lobbyist, A11). The amount and complexity of the proposals, together with the lack of resources, were challenging for nongovernmental organizations (NGOs), but public apathy also proved to be problematic, as public politicization is typically a vital resource for NGOs.

The Commission's Informal Role as Mediator

Representatives from the Commission attended all Council and EP meetings, which provided the Commission with the opportunity to mediate a compromise. In this context, several interviewees stressed that the Commission had a monopoly on information (A1, A6, A8, A12, A14). Others reported that the Commission official from DG Enterprise who was in charge of the dossier was very knowledgeable and defended its proposals in a rather aggressive way. He did not appreciate concrete amendments during the Council working group (A5, A7, A9). A DG Enterprise officer noted about the process, "The more complicated [it is], the more important it is to have somebody who completely understands the entire system. And as this is a complicated package, yes, probably the expertise inside the Commission gave it a certain influence" (DGE officer, A1).

In addition, the Commission's DG Enterprise threatened the Council with a worst-case scenario if the review was not completed before May 1, 2004, when ten new member states came on board. As one interviewee recalled, "The first of May 2004 was a fatal date. A new Parliament, twenty-five member states, the whole discussion would have started all over again. Thus, it was inescapable for the old member states to finish it before May. I think the Commission consciously anticipated it" (Dutch civil servant, A7). Another remembered the Commission being "absolutely determined to get this agreed, to avoid reopening the negotiations" (British civil servant, A6).

The Commission did not act as a mediator. Once its agenda was set, the Commission constantly pressured the member states to fall in line; it did not actively search for a compromise on data exclusivity, but insisted on adoption of the "correct balance" it had formulated. In addition, it "was more inclined to seek and build alliances with the rapporteurs in the EP

than with the various member states. . . . The EP rapporteurs and the officials from the Commission seemed to be in close contact throughout the process" (Danish civil servant, A3). This was confirmed by a representative from DG Enterprise as well. The influence of the Commission on the EP "depends a bit on the rapporteur, but we had one rapporteur from the Socialists and one from the Conservative Party. Both had very close contact with the Commission" (DGE officer, A1). It seems plausible that the Commission preferred to work together with the EP: first, the codecision procedure gave the EP a strong position, and, second, the Commission needed to work only with the two rapporteurs, instead of fifteen member states.

Codecision and Informal Trialogue: The Role of the European Parliament

The influence of the EP under codecision depends on the expertise in the Committee as well as the acceptance of its amendments by both the Commission after first reading and the Council in its common position or during the (in)formal conciliation. Normally, there are no time limits during its first reading. MEPs involved "view it as a period for discussion, for gathering expertise, laying down their respective positions, and clarifying (mainly) technical questions" (Neuhold 2001). However, because of time pressure created by the upcoming enlargement, "the EP did not control the amount of issues" (Danish civil servant, A3). Still, the issue of data exclusivity was highly politicized and therefore generated much debate.

During the EP plenary meeting (first reading) in October 2002 (European Parliament 2002a), both rapporteurs emphasized the importance of competitiveness in relation to data exclusivity. According to Grossetête (France, European People Party), "we all know that innovation comes at a price. Industry therefore needs to guarantee the protection of this data. It is our duty to encourage research to ensure that science moves forward." Müller (Germany, European Socialists) argued that "the harmonization of data exclusivity is certainly a step towards increased competitiveness. . . . The ten-year rule gives a signal to pharmaceutical companies to intensify research and market truly innovative products. However, it also gives a signal to generic drug manufacturers to use the Bolar provisions" (ibid.).

Other MEPs opposed these arguments. Ainardi (France, European United Left) argued that "the — apparently essential — aim of the proposals . . . is to strengthen the short-term competitiveness of pharmaceutical companies" (ibid.). Corbey (the Netherlands, European Socialists) pointed

out that lengthening data exclusivity "is no guarantee for innovation. Quite the opposite, in fact; there is more innovation happening in the United States, which has a shorter period of protection" (ibid.). After long deliberations, the EP came up with a different balance than the Commission did (the 8 + 2 + 1 formula instead of the 10 + 1 formula; see also European Parliament 2002b). Following this outcome, the Commission rejected almost all of the first reading amendments related to data exclusivity.

In the EP's second reading, the Council's common position may be accepted, rejected, or amended. The Commission believed there was enough common ground between the Council and the EP to reach an agreement before the second reading, and it initiated an informal trialogue to iron out differences. This was of major importance, because "the formal conciliation procedure would not fit the time schedule" (German civil servant, A8). To speed up this process and increase the likelihood of a compromise between the Council and the EP, informal talks were held between DG Enterprise, the rapporteurs of the EP Public Health Committee, and the Italian presidency of the Council as of September 2003.

According to one interviewee, the trialogue is an instrument used to avoid unexpected steps of the EP during the second reading (Belgian policy expert, A15). However, in early December the Public Health Committee reinstated all its amendments of the first reading regarding data exclusivity, which had not been accepted by the Council. In case these amendments were adopted by the EP plenary, conciliation between the EP and the Council would be necessary. Under these circumstances, agreement before the deadline was not likely. This shows that the EP was willing to risk delaying the whole process.

Several interviewees emphasized the importance of the EP: "In very broad terms the EP played a greater role than at least I had imagined from the outset" (Danish civil servant, A3). Generally speaking, as one put it, "all parties, including the EP, are beginning to realize just how much power they now have. I mean, they are a true party to the discussions with this codecision procedure. And of course, they get the final word really in their second reading" (British civil servant, A6). Indeed, the Parliament was instrumental in proposing the compromise solution.

Codecision: Lobbying the European Parliament

The role of lobbyists in the EP is an important one. They try to influence MEPs by giving them information, and MEPs regard them as a source of information to understand key points and conflict issues. One interviewee

noted, "A massive package like the pharmaceutical review comes to the limits of what the legislative machine in the EU can do. Clearly, the EP is having difficulties . . . grasping the technical details" (DGE officer, A1). This was confirmed by other interviewees: the EP often does not have the necessary knowledge because of the technicality of certain issues, which increases the influence of industry lobbyists (A9, A10, A13). In the case at hand, a Dutch civil servant said that representation by pharmaceutical companies and associations was phenomenal, powerful, and also influenced the EP Public Health Committee (Dutch civil servant, A5). A Danish civil servant confirmed this: "The influence of the industry on various MEPs was to a large degree obvious from the language of many amendments" (Danish civil servant, A3).

In response to the industry lobby, a group of French consumer, patient, and insurance organizations, together with the association Mieux Prescrire and the International Society of Drug Bulletins, launched the so-called Medicines in Europe Forum (MiEF) in March 2002. According to the MiEF, the public health perspective was not adequately taken into account. It claimed that the Commission considered pharmaceuticals as normal industrial goods, seeking to reinforce short-term competitiveness of European pharmaceutical companies by prolonging data exclusivity (Editorial: A Free Hand 2002).

The MiEF did not influence the process of agenda setting on data exclusivity, because it was only established after the proposals had been created. It therefore mainly concentrated on lobbying the EP: "We found no historical reasons and no rationale for extending the monopoly position of originator drugs, and the Commission offers no figure to support their current position. The proposed extension is clearly not intended to compensate manufacturers for time lost in administrative procedures . . . . This is quite enough: no further lengthening of the data protection period is justified" (Medicines in Europe Forum 2003).

Qualified Majority Voting in View of EU Enlargement: Searching for a Compromise in the Council

Most member states discussed the review with their national pharmaceutical industries. This was not considered interest representation, but rather a necessity, given the review's direct impact on the industry. It was considered important to understand the position of the industry in order to develop policy positions on various issues (A6, A8, A9). One interviewee

stated, "We have had much contact with EGA, [which] was very active, and on the issue of data exclusivity did everything to promote the point of view of the generics industry" (Dutch civil servant, A9). Another interviewee said that "whilst [the pharmaceutical industry] did not drive government policy, . . . we did take account of what the industry's concerns were . . . . They did not have to lobby; they had access to us" (British civil servant, A6).

In the Council working group, the Commission's proposal on data exclusivity caused a lot of discussion, because half of all member states and all ten accession countries would have had to increase their exclusivity period from six to ten years. As of January 2003, the accession countries joined the Council's pharmaceutical working group: "Everybody knew they had no voice. They were listened to politely, but in the end they did not have any power to really say what they wanted" (Dutch civil servant, A5).

Various exclusivity periods were suggested, depending on the marketing authorization procedure used (the centralized or mutual recognition procedure). Given that member states had widely diverging preferences, the informal consensus rule did not play a role: "If you want results, you must compromise. The point of unanimity was not discussed" (German civil servant, A8). However, achieving something of a shared vision took a long time (Dutch civil servant, A5).

In this case, the Council's organization was perceived to be a problem. Some member states were represented by their permanent representations in Brussels. Though they understood politics, the technicality of the proposals and their involvement in many different subjects was considered a disadvantage. Those countries that were represented by technical experts were strong on content but generally lacked insight in EU politics (A12, A15). In addition, these experts were responsible for marketing authorizations as such, lacking any reflex to take health care costs into consideration (Belgian policy expert, A15).

Generally, in cases where the Council acts on complex technical matters, its decisions often support the Commission's original proposal (Majone 1996: 73). However "the negotiations were as much political as getting the framework right from a technical point of view" (British civil servant, A6). The time pressure, though, did have its impact on the negotiations. Several interviewees claimed that member states would have preferred to discuss many items more thoroughly (A8, A9, A12). When the date for accession for the ten new member states was agreed, the Council recognized "that there were going to be significant difficulties in getting the ten

member states, because of who they are and their history, to support the ten-year data exclusivity period . . . . That really makes you think, 'Well, in that case maybe there are some concessions I can make in order to finalize this before the enlargement' " (British civil servant, A6). Some perceived the review as "the most appalling example of misgovernance, because the extension of data exclusivity was pushed through and the pharmaceutical review was fast-tracked before enlargement . . . . [The accession countries] were totally ignored. Frankly, the interests of the industry largely based in countries like France, the United Kingdom, and Germany, prevailed over the wider solidarity issue or even the general health issues" (PH lobbyist, A11). At the same time, some member states kept raising problems to be able to exchange in the end for the final compromise (A5, A8).

Because no compromise could be found at working group level, data exclusivity needed to be discussed at ministerial level. Prior to the Council meeting of June 3, 2003, the smaller member states with six years of data exclusivity formed a blocking minority. Finland and Denmark stated that they could not accept data exclusivity beyond eight years, whereas several other member states, including Germany, France, Italy, and the United Kingdom, wanted to adopt the Commission proposal. In the end, the compromise proposal of the Greek presidency was accepted, namely the 8 + 2 formula for pharmaceutical products authorized via the mutual recognition procedure (i.e., "harmonized" national authorization valid in selected member states) and the 10 + 1 formula for pharmaceutical products authorized via the centralized procedure (i.e., single Community authorization valid in all member states). This shows that harmonization was not the Council's priority.

The concept of data exclusivity had already been introduced in 1987, therefore representing an irreversible path. The discussion about whether it would stimulate innovation was past due. The Council debate focused on how long data exclusivity should be. Opposition to the 10 + 1 formula was voiced by a coalition of member states, including accession countries with little or no innovative industry. Their focus was on health care cost control. Member states with a strong innovative industry that already had ten years protection at the national level were in favor of the 10 + 1 formula. However, even those countries had to take their generics industry and health care costs into account. Therefore, during the informal trialogue, the seeming compromise of the 8 + 2 + 1 formula, as suggested by the EP, was acceptable for them in the end.

According to a representative from the Commission, if the package had been finalized after the first of May 2004, "the final outcome would

not have been eight plus two" (DGE officer, A1). This was confirmed by another interviewee: "The ten new member states could quite reasonably have said, we need — we have the right — to discuss and debate every provision in this legislation" (British civil servant, A6). The result would have been a different balance between more innovation and lower prices.

Health ministers of the candidate member states signed the so-called Milan Declaration in September 2003, emphasizing the priority of retaining six years, since generics made up a vital share of their markets. They held that data exclusivity up to ten years would "weaken the availability and affordability of medicines to the public, place greater burden on the national health insurance fund, and have a negative impact on the fragile national pharmaceutical industry" (Ministers of Health of the Acceding Countries 2003). But the declaration was largely a symbolic protest, because the candidate member states could only participate as observers and never had the possibility to influence the process according to their own preferences.

Discussion

This analysis shows that industrial interests of innovative companies prevailed over the interests of others, including the generics industry, consumers, patients, and member states interested in controlling pharmaceutical expenditures. The legally required pharmaceutical review constituted the opening and EU enlargement in May 2004 formed the closing of a window of opportunity during which the revision of data exclusivity could take place (Feick and Broscheid 2005: 33). A combination of factors explains the final outcome.

Initially, DG Enterprise, together with EFPIA, developed the proposal on data exclusivity behind closed doors. However, the position of the EP and the member states in the Council had to be taken into account as well. A coalition of member states with strong research-based industries, the research-based industry itself, and the Commission were in favor of long protection periods. Opposition was voiced by the EP, the generics industry, and some member states, including accession countries with no or little research-based industry and an interest in the containment of health care costs. From the perspective of these countries, major regulatory and institutional changes were imposed on them just as they were joining the EU. However, even member states with a strong research-based industry "had to consider the interests of [their] generics producers and healthcare institutions" (Feick and Broscheid 2005: 19).

It was the Commission's DG Enterprise that stressed the importance of a long data exclusivity period, rather than the health and consumer protection department of the Commission, DG Sanco. Since the Commission had industrial but no health care policy competences, there was a convergence between the interests of the research-based industry and the industrial policy concerns of DG Enterprise (Permanand 2006: 9). They had the same agenda: promotion of the research-based industry.

This case makes clear the European Commission's strong control of legislation at each juncture in the process, as well as the crucial nature of the specific Directorate-General of the Commission responsible for an area. The pharmaceutical division of DG Enterprise is the driving force behind harmonization of the internal market, in this case to maximize profits for the innovative portion rather than maximize market competition. The European agenda for pharmaceuticals is a DG Enterprise agenda, that is, high-tech economic growth.

Our analysis also makes clear that the innovative industry lobby (EFPIA) provided the expertise and guided DG Enterprise, capitalizing on a huge industry review and on the argument that it would be harder to press their case for more market protection through longer data exclusivity after ten more members joined the EU. EFPIA was, in fact, very successful in convincing the Commission, through DG Enterprise, to adopt a proposal for ten years and to help push it through.

Data exclusivity appears to be one of several strategies by the research-based industry to delay generic price competition. A recent study by DG Competition of the European Commission has found that "in many instances originator companies use two or more instruments from the 'tool box' in parallel and/or successively in order to prolong the life cycle of their medicines" (Commission of the European Communities 2008: 294). These instruments notably include secondary patenting,[12] patent-related contacts and disputes, litigation, settlements, and interventions. From 2000 to 2007, the research-based industry initiated nearly seven hundred lawsuits covering patents and data exclusivity, even though "the claims of the originator companies were upheld in only 2% of the cases" (Commission of the European Communities 2008: 294). DG Competition of the European Commission concluded that these tactics "significantly increase legal uncertainty to the detriment of generic entry and can cost public health budgets and ultimately consumers significant amounts of money" (ibid.: 13).

12. When the main patent is about to expire, companies apply for a subsequent patent for the same initial molecules, while adding some degree of innovation.

Framing data exclusivity in terms of innovation was the industry's successful effort to persuade European leaders and the EU that Europe had lost its leadership in discovering important new drugs and become eclipsed by the United States as the dominant source of innovation. The industry influenced DG Enterprise to commission several reports between 1994 and 2004, each of which came to this strong conclusion. Yet a new analysis of the evidence provided has found that the data and facts in these reports do not support their conclusions (Stolk and Light 2008). In short, DG Enterprise helped the pharmaceutical industry promote an unsubstantiated threat that has served to make member states and the EP eager to do anything to strengthen Europe's position, including establishing the world's longest market protection from data exclusivity.

For the past decade, the pharmaceuticals unit of DG Enterprise has been promoting for the pharmaceutical industry an end to the ban against direct-to-consumer advertising (DTCA) of prescription drugs (Boessen 2008). This complements campaigns to maximize market protections from generic price competition through data exclusivity and patent disputes, because it would increase sales and range of uses during the period of market exclusivity. From the perspective of patients and public health financing, the implications of DG Enterprise having written and orchestrated all phases of new legislation is troubling.

The question that now needs to be debated and informed by this case study is how pharmaceutical policy can be developed in a way that takes into account the need of countries to manage rising costs to receive good value and their need to reward innovation while benefiting from generic price competition, which acts as the spur for innovation.

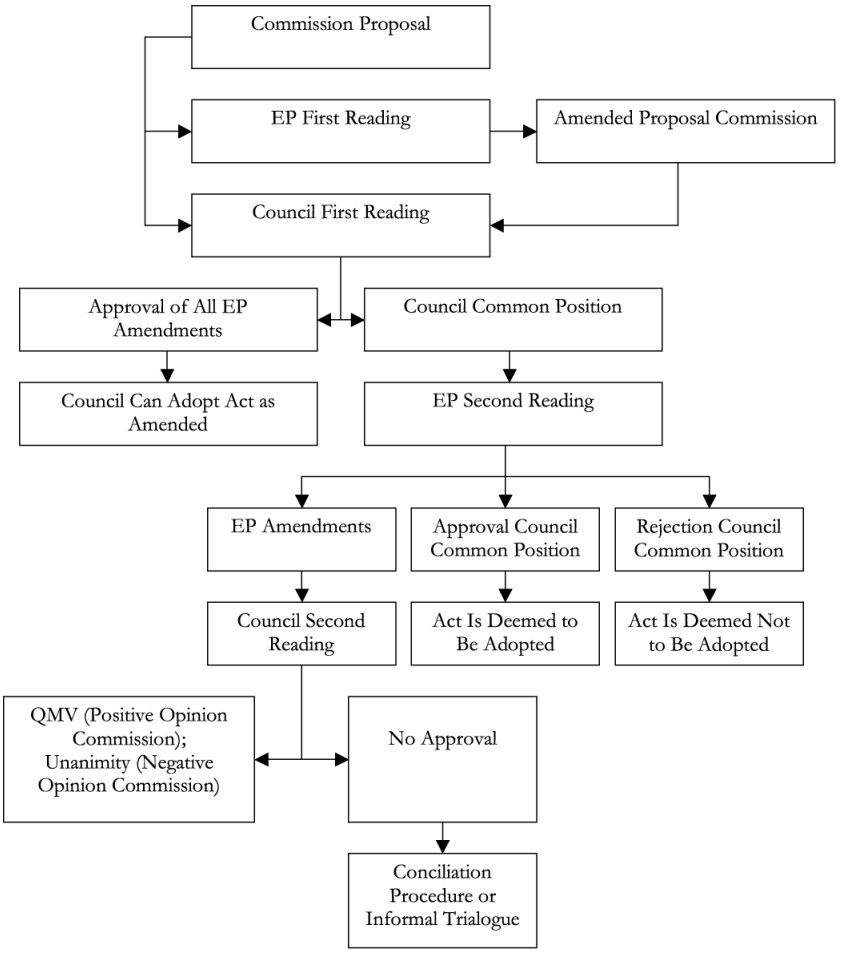
Appendix A: Interviews October 2006–December 2007

We recorded and transcribed all the following interviews, which were conducted in confidentiality. Both the tapes and transcriptions are in possession of one of the authors. We began each interview with a general question: "What was your role in the negotiating process concerning . . . ?" This approach allowed the interviewees to provide an open answer before specific questions related to strategic behavior were asked. The function of the interviews in our research was to increase our insight into differing viewpoints, interpretations, and perceptions of policy making.[13]

1. Officer, DG Enterprise, European Commission, October 18, 2006
2. Officer, DG Sanco, European Commission, October 18, 2006
3. Danish civil servant, November 20, 2006
4. Pharmaceutical policy consultant Burson-Marsteller, November 4, 2005
5. Dutch civil servant, June 29, 2006
6. British civil servant, January 17, 2007
7. Dutch civil servant, October 31, 2006
8. German civil servant, January 9, 2007
9. Dutch civil servant, November 15, 2006
10. Dutch member of the European Parliament, October 23, 2006
11. Lobbyist, public health organization, November 9, 2006
12. Lobbyist, European Generics Association, November 9, 2006
13. Lobbyist, Medicines in Europe Forum, February 16, 2007
14. Lobbyist, British consumer organization, December 5, 2006
15. Belgian European policy expert, December 4, 2007
16. Lobbyist, public health organization, December 6, 2007

13. We were not able to talk to a representative from the European Federation of Pharmaceutical Industries and Associations. We attempted to contact the person responsible via e-mail and telephone, but even after repeatedly talking to the secretary who promised to get back to us, no one ever contacted us.

Appendix B: Codecision Procedure



Notes: EP = European Parliament; QMV = qualified majority voting

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