# COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a

COUNCIL REGULATION (EEC)

concerning the creation of a supplementary protection certificate for medicinal products

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(presented by the Commission)

## EXPLANATORY MEMORANDUM

### Summary

Introduction: Subject and scope of the proposed Regulation

Part One: Outline of the proposal

1. Aims
2. Details and characteristics of the proposed system
3. Need for and scope of a Community solution
4. Legal basis

Part Two: Examination of the provisions

EXPLANATORY MEMORANDUM

## Introduction: Subject and scope of the proposal

1. The aim of this proposal for a Regulation is to improve the protection of innovation in the pharmaceutical sector. In this respect, it forms part of Community health policy, which seeks to create the conditions which permit the European pharmaceutical industry, by the turn of the century, to guarantee therapeutic, scientific, economic and social progress which is indissolubly linked with the discovery and use of new medicinal products.

2. Patents still represent the best tool for protecting innovation in this respect. There is, however, the risk that this will no longer be the case if an appropriate adaptation to evolving needs is not duly taken into account.

   Innovation in the pharmaceutical field is particularly threatened in this respect.

   The duration of patent protection in Europe today is generally 20 years from the date on which the patent application is filed. This is the duration laid down in the European Patent Convention (Munich) and in the national laws of most of the Member States of the Community.

   Once a patent has been granted, the patent holder may, in principle, immediately make use of the invention concerned on the market. Such use may even be made before the patent has been granted.

   However, this is not the case as far as medicinal products are concerned. The holder of a patented medicinal product must refrain from using it until he has obtained authorization from the health authorities to place the product on the market.

Prior authorization procedures for medicinal products were first introduced in the industrialized countries following the experience with thalidomide. Since then, the public authorities have required the pharmaceutical industry to demonstrate the quality, safety and efficacy of new medicinal products. These prior controls, which are essential for the protection of public health and which are beyond question, involve considerable scientific and technical effort and expenditure.

However, it should be pointed out above all that the manifold (physico-chemical, biological or microbiological, toxicological, pharmacological and clinical) tests required to compile the application which will be submitted to the health authorities and the procedure itself for obtaining authorization involve elapses of time which are becoming increasingly longer and are often proportional to the importance of the innovation.

This leads to a corresponding loss of a very substantial part of the period of exclusivity granted by the patent. An average period of 12 years between the discovery of a new medical product, at which time the patent application is filed, and its being made available to patients is currently necessary, the effect of which is to reduce the exclusive exploitation period under the patent to only 8 years.

3. This situation, which has come about as a result of interference between two types of administrative procedure, imposes heavy penalties on pharmaceutical research, which is therefore discriminated against as compared with other technological sectors.

It is true that this interference also takes place in other industrial sectors, in particular the agro-chemical sector, the food sector, etc., but it is undisputed that the pharmaceutical sector is clearly the most affected. It is furthermore the only one which, for many years, has been asking the public authorities to find a solution.

The European Federation of the Pharmaceutical Industry Associations published in 1988 a "Memorandum on the Necessity to restore the effective duration of patents for pharmaceutical products"; moreover, additional industry contributions documenting the problem of pharmaceutical product patent erosion were sent to the Member States in 1989.

In 1980, the Commission took the view that it was necessary to protect innovating firms. Directive 87/21/EEC therefore introduced, without prejudice to patent protection, a mechanism which, in particular for "high-technology" medicinal products, prevents a second applicant for marketing authorization from presenting a smaller-scale application for a period of 10 years from the first authorization for marketing of the product in the Community.

The Commission takes the view that it is time to protect further new medicinal products, but that it would be premature to make this proposal a measure of general application without having assessed the need for such a generalised measure or the urgency therefor.

Nevertheless, although it is confined for the time being to medicinal products, the Commission does not exclude the possibility of a medium-term adjustment which, while extending the effects of the proposal to other categories of products, might provide either for a similar or a different legal mechanism, in light of the circumstances and the experience gained in the pharmaceutical sector.

4. Far from being a discriminatory measure in favour of a particular sector, the present proposal for a Regulation aims at guaranteeing laboratories working to develop new medicinal products a level of protection equal to that enjoyed by research in other sectors.

The manifold consequences of maintaining the status quo are reasons enough to have convinced the Commission of the need to try to find a solution at the Community level adapted to the particular problem and taking balanced account of all the legitimate interests involved.

## Part One: Broad outline of the proposal for a Regulation

### A. Aims

5. More than in any other sector, research is particularly vital to the pharmaceutical industry itself and to society as a whole. There is no substitute for innovation in the case of medicinal products.

European industry allocates between 10 and 15% of its turnover for pharmaceutical research and is virtually self-financing. It is a high-risk activity in which investments are extremely costly and hazardous. Out of a total of about 10,000 substances synthesized by a research laboratory, a few hundred will be selected for the filing of patents out of which only one to three will actually be authorized to be placed on the market.

The patent protection system is therefore essential to this innovating sector, in that investment in research is financed by means of returns obtained during a period of exclusive exploitation, thereby making it possible to ensure that self-funding continues and to guarantee further research in the future.

6. Over about the last 10 years there has been a fall in the number of molecules of European origin that have reached the research and development stage (40% as against 65% 10 years ago) and a slow erosion of European market shares as compared with those of the USA and Japan.

With regard to the latter, it should be noted that, apart from a general context which is more favourable than that of the Community, notably as regards social security systems, price levels and the relative size of the national markets, US and Japanese companies have, since 1984 and 1988 respectively, benefitted from patent term restoration for pharmaceutical products on their national markets.

7. The Commission is of the opinion that a passive attitude to the current situation will entail two types of risk for the Community, on the one hand, a decrease in research due to insufficient resources and, on the other hand, the relocation of research centres away to non-member countries that offer better protection and an environment more conducive to innovation.

   Furthermore, the existence among the Member States of the Community of several parliamentary initiatives, of which one is at a very advanced procedural stage, providing for supplementary protection for patented medicinal product leads to the necessity to harmonise national developments at the Community level.

8. The basic objectives of this proposal for a Regulation therefore concern the requirements relating to the proper functioning of the internal market, improvement of our competitiveness as compared with that of our trade partners and the encouragement of research and development in the health field.

B. <u>Details and characteristics of the proposed system</u>

(a) Details

9. The proposal for a Regulation provides for the creation of a protection certificate <u>sui generis</u> in the form of a supplementary protection certificate.

   This certificate will be granted by the patent office in each Member State at the request of the holder of a (national or European) "basic" patent relating to a product authorized to be marketed in the State concerned.

   The same medicinal product that is patented and authorized to be marketed in several Member States may therefore be the subject of as many national certificates, the conditions for obtaining which, the basic details and the duration of protection being laid down uniformly for the entire Community territory.

The certificate confers the same protection as the basic patent, but only protects the product covered by the authorization, for all pharmaceutical uses authorized, until the expiry of the basic patent.

The certificate is linked to both the marketing authorizations system and the patents system in such a way that it becomes void in particular if the authorization is not valid or if the basic patent is revoked.

(b) Characteristics

- A balanced system

10. The proposal for a Regulation as a whole constitutes a balanced system since each of its essential features has been determined in the light of the aims of the proposal and the interests involved. The Commission takes the view that the proposed system should be effective and appropriate for the industry's requirements without neglecting other substantial aspects of national and Community health policy.

11. The proposal for a Regulation therefore concerns only new medicinal products. It does not involve granting a certificate for all medicinal products that are authorized to be placed on the market. Only one certificate may be granted for any one product, a product being understood to mean an active substance in the strict sense. Minor changes to the medicinal product such as a new dose, the use of a different salt or ester or a different pharmaceutical form will not lead to the issue of a new certificate.

12. However, the proposal is not confined to new products only. A new process for obtaining the product or a new application of the product may also be protected by a certificate. All research, whatever the strategy or final result, must be given sufficient protection.

13. The certificate does not protect the expired patent in its entirety. It protects only the product authorized to be placed on the market. Furthermore, account is taken of the process of development of the product for the purpose of obtaining the authorization in such a way that the protection afforded to the product is linked to the uses for treatment which were authorized during the life of the patent.

14. The duration of the protection given by the certificate is set in such a way as to enable it to afford actual overall protection similar to that in other sectors of technology. This period is set at 16 years in the proposal. However, it is set as a function of the first marketing authorization in the Community, which means a loss to industry in countries in which the authorization is granted much later.

Moreover, the duration of the protection given by the certificate may not under any circumstances exceed 10 years. The purpose of this is to set a cut-off point to penalize against authorizations obtained at a very late date (more than 15 years after the filing of the patent) and to compensate in some way for the lack of supervision of the undertaking's diligence as regards the management of the health dossier.

15. The proposal provides for a transitional arrangement to take account of the fact that the problem of the erosion of patents in the pharmaceutical field exists at present for medicinal products which have already been placed on the market and that it would be illogical to disregard such products completely at the time when a solution is adopted. Furthermore, there is the danger that a gap will develop between the expiration of some major pharmaceutical patents and the discovery of products developed from new technologies which could jeopardise the cycle of self-financing research if medicinal products concerned were not able to benefit from being granted a certificate.

Lastly, it is to be hoped that the European pharmaceutical industry will be able to close some of the gap which has arisen between itself and its major competitors in the international market. In the USA, the Waxman-Hatch Act entered into force in September 1984. In Japan, the revision of the Patents Law took effect on 1 January 1988.

- A simple, transparent system

16. The proposal for a Regulation provides for a simple, transparent system which can easily be applied by the parties concerned.

It therefore does not lead to excessive bureaucracy. There is no need for any new administrative body and the patents offices should be able to implement the procedure for granting the certificate without an excessive burden being placed on their administrations.

The documents required to file an application for a certificate are limited to what is strictly necessary to enable the offices to take a decision on granting the certificate or to reject the application. Examination of the conditions to be fulfilled for the certificate to be granted involves the use of objective data that are easy to verify. However, coordination with the health authorities could be provided for by the Member States if they consider this to be necessary.

The adoption of a standard system to calculate the duration of the protection given by the certificate without abstraction of certain information specific to the case (date of granting the authorization, date of filing the patent application, date of expiry of the patent) means that the calculation is easy to make.

17. The procedure envisaged lastly guarantees the transparency of the system since the decision to grant the certificate and the application are both published, the latter having been filed sufficiently early after marketing authorization was given to enable third parties to be swiftly informed.

C. Need for and scope of a Community solution

18. In view of the problem of the erosion of patents in the pharmaceutical sector, a genuine European market cannot accommodate ex novo national solutions that might affect the free movement of medicinal products and the competition rules within the Community.

A Community solution entailing harmonization of the conditions for the application of the system introduced and the rules governing it and standardization of the duration of protection of medicinal products therefore has to be found to secure the establishment and proper functioning of the internal market.

19. However, with regard to patents, the national laws cannot be approximated without also preserving harmonization between the national systems and the European patent system. It specifically has to be avoided that, within one and the same Member State, new medicinal products enjoy an overall period of protection that differs according to whether the patent was granted under the national laws or under the European Patent Convention to which, on 1 January 1990, there were 14 contracting States, of which 10 are in the Community (with the exceptions of Ireland and Portugal) and four are States of the European Free Trade Area (Switzerland, Austria, Sweden and Liechtenstein).

This logical need for harmonization at two levels could theoretically be met if a Community Directive applicable only to medicinal products protected by a national patent were accompanied by a partial revision of the European Patent Convention to provide similar protection for medicinal products protected by a European patent.

However, it would not seem to be possible to provide in the short term for the revision of the European Patent Convention or for such a revision to be adopted unless this is done by the Member States acting unanimously, since Article 172(a) of the Convention provides that States which do not ratify or accede to a revised text of the Convention shall cease to be parties to it.

These facts have prompted the Commission to seek to find a Community solution applicable to all medicinal products authorized to be placed on the market and protected by a patent in their territory whatever path - national or European - has been followed for that purpose.

20. The proposed system takes the legal form of a new protection certificate, sui generis, which is national in character and lies at the interface between two systems, that of prior authorizations for the placing on the market of medicinal products and that of their protection by patent, and which confers on the system its specific characteristics and special nature.

These can be seen first of all in the scope of the certificate and the conditions for obtaining it. They can also be seen in the subject of the protection, which is limited both by the authorization itself since the protection extends only to the authorized product and only for the therapeutic uses of it which were the subject of an authorization, and in the claims of the basic patent.

They can also be seen in the fact that the non-validity of both the authorization and the patent render the certificate void.

The certificate is therefore a national document harmonized at the Community level and is essentially different from the basic patent.

Furthermore, it may not under any circumstances distort the operation of the European patent system. The result would be completely different if it were possible to obtain a certificate only for medicinal products protected by a national patent.

21. A fortiori, when use is made of the European procedure to obtain a Community patent, it will likewise be necessary that the certificate can apply equally to medicinal products protected by a Community patent. The proposal has been developed with a view to applying equally to such an eventuality, with minor modifications, if necessary.

22. It should, lastly, be pointed out that, as part of the overall process of alignment between the EEC and the EFTA which may result in a wider European economic area, the Commission has taken care, since a possible Community solution to the erosion of pharmaceutical patents was first mooted, to inform the EFTA Member States and to involve them in joint deliberations.

23. A Community solution is justified by the fact that any measure affecting health must be considered in an appropriate context. Where appropriate, the Community institutions will hold political discussions on measures that form part of Community health policy.

With regard to the health field, the Commission is aware that objections to this proposal for a Directive will be expressed. Far from ignoring the arguments of those concerned, the Commission has taken account of them in its proposal.

24. The argument concerning health and social security costs is no doubt the most important. Health expenditure is rising continuously throughout the world. At the same time, the shortfalls in the social security systems are a subject of concern to those with political responsibilities. It is therefore legitimate to question the possible effects of this proposal for a Regulation on costs.

The system established by the proposal does not apply to all patented medicinal products placed on the market, but only to those which consist in new medicinal products. . A large proportion of the medicinal products sold on the market have only few innovative features, or none at all. These are not covered by the scope of the proposal. Each year, only about 50 new medicinal products are authorized worldwide. It is these that are covered by the proposal for a Directive. As for the transitional arrangement provided for in the proposal, the aim of this is to strike a fair balance between what industry needs and what can reasonably be accepted by society.

Furthermore, the proposal for a Regulation does not affect the Member States' ability to control the prices of medicinal products on their markets.

Lastly, the present proposal, moreover, favours a possible fall in the prices of the medicinal products covered by this proposal in light of the extension of the period for recuperation of investments.

25. Another argument concerns the effect of the proposal on the access of generic products to the market and therefore of competition within the Community between research based industry and producers of generic products.

It is true that the longer the exclusivity period, the longer the delay before generics enter the market. The aim of the proposal is specifically to ensure that research based industry has a market exclusivity of sufficient length to permit recovery of their investments.

However, this will not mean any reduction in competition. The well known effect of the patents system is to promote competition through innovation. For this, a balance is struck between the encouragement of innovation and the making of innovations available to society by disclosing them. Generic products exist only if new medicinal products are developed and disclose. Producers of generic products therefore have every interest in not seeing research being stifled.

Furthermore, the Commission would point out that, to reach the market place, generic products must meet the same quality, safety and efficacy criteria as are required for new medicinal products if it is wished to maintain public health in Europe.

In devising the proposal, the Commission has taken care to strike a balance between the interests of researchers and those of generic firms, notably in laying down the duration of the protection given by the certificate and the transitional arrangements.

26. In conclusion, the debate on the patentability of medicinal products has already taken place in all of the Member States and everyone has endorsed an alternative of effective protection for research. This has helped to put Europe in the forefront as far as the quality of public health is concerned. It is now a question of making coherent use of the options that Europe has chosen.

## D. Legal basis

27. The introduction of a different period of protection for medicinal products in each of the Member States of the Community would create obstacles to their free movement within the internal market and distort the conditions of competition.

The introduction of a standard, adequate period of protection for the results of pharmaceutical research, on the other hand, will be sure to encourage innovation and technical progress at Community level and to promote intra-Community trade in medicinal products.

The Commission proposes to take Article 100a of the EEC Treaty as the legal basis for this proposal.

In drafting the proposal, the Commission has taken due account of the provisions of Article 8c of the Treaty and has found that there is no need to provide for special or exceptional provisions for the time being.

Similarly, the Commission has considered the question of the high level of protection required in the field of health, safety, environmental protection and consumer protection under Article 100a(3) of the Treaty. It has taken full account of these aspects in the proposal.

## Part Two: Examination of the provisions

### Article 1

28. The concept of a medicinal product as used in everyday speech is more difficult to define in legal terms.

Furthermore, since the objectives of the patent system are different from those of the system of marketing authorization, the definition of a medicinal product in pharmaceutical law cannot be taken to be exactly the same as that in patent law.

What is authorized to be placed on the market is referred to as a "proprietary medicinal product", i.e. "any ready-prepared medicinal product placed on the market under a special name and in a special pack" (Article 1.1 of Directive 65/65/EEC).

However, it may be the medicinal product that is patented, meaning the active ingredient, the process by which the medicinal product is obtained, or an application or use of the medicinal product.

For the purposes of the certificate, which lies at the interface of the two systems, the terms "product" has been chosen as a common denominator. The exact meaning given to it is defined in Article 1, which is based on the definition of a medicinal product laid down Directive 65/65/EEC. However, the qualifier "active" is added to the term "substance" in order to include the concept of an "active ingredient or "active substance" used in patent law.

Consequently, the term "product" is not understood to mean a proprietary medicinal product or a medicinal product in the wider sense, but in the narrower sense of product used in patent law which, when applied to the chemical and pharmaceutical field, means the active ingredient.

29. The purpose of the expression "product protected by a patent" is to specify what types of invention may serve as a basis for a certificate.

The proposal does not provide for any exclusions. In other words, all pharmaceutical research, provided that it leads to a new invention that can be patented, whether it concerns a new product, a new process for obtaining a new or known product, a new application of a new or known product or a new combination of substances containing a new or known product, must be encouraged, without any discrimination, and must be able to be given a supplementary certificate of protection provided that all of the conditions governing the application of the proposal for a Regulation are fulfilled.

Article 2

30. This Article determines the scope of the proposal. It refers to any product that is the subject of both a system of protection by patent and a system of administrative authorization prior to its being placed on the market. It is specified that the authorization concerned is that provided for in Directives 65/65/EEC and 81/85/EEC, thereby making it clear that the proposal applies only to medicinal products for human or veterinary use. On the other hand, the text does not state under what kind of law patent protection is given and it follows from this that the proposal applies to all pharmaceutical products protected by patent in all of the Member States, whether this be a national patent, a European patent or, in due course, a Community patent. Lastly, mention is made of the legal instrument used to resolve the problem at hand.

31. Only patented products are covered, whatever the legal source of the patent. With a view to the single market, the national patent laws must not be harmonized without harmonization also being maintained between the national patent systems and the European system. In the present case , it is a question of preventing the pharmaceutical industry from being faced with the illogical situation whereby, in one and the same Member State, a new medicinal product may or may not benefit from the application of the Regulation depending on whether the corresponding patent was obtained nationally or at the European level.

The two-level harmonization required, in addition to which there is in this specific instance a certain urgency in view in particular of the lead gained by the US and Japanese legal systems and, moreover, the constantly increasing periods required to obtain authorizations to place products on the market, calls for the adoption of a legal solution that maintains such harmonization and enables it to be implemented simply and swiftly. For this purpose, the proposal for a Regulation proposes the creation of a protection certificate sui generis, this being a supplementary protection certificate, the conditions and the rules for obtaining which are laid down in a uniform manner for all of the Member States of the Community.

Article 3

32. This Article lays down the basic conditions to be met by a product in order to obtain a certificate. As the certificate is a national document, compliance with these conditions must be examined with respect to the Member State in which the certificate application is submitted and to the application date.

33. First, it has to be verified whether the product is protected by a patent in force. It is this patent that serves as the basis for the certificate for the purposes of the proposal for a Regulation.

It may be that the product is protected by several patents, e.g. by a patent for a product and a patent for the procedure used to obtain the product. In this case, it is for the holder of the patents concerned to chose one of them as the basic patent. This choice is particularly important if the subject and the content of the protection granted by the certificate are respectively limited by the subject and content of the basic patent.

34. The product must have obtained a valid marketing authorization in accordance with Directive 65/65/EEC or Directive 81/851/EEC, depending on whether it is a medicinal product for human use or a veterinary medicinal product. More specifically, what is authorized to be placed on the market is what Directive 65/65/EEC refers to as a proprietary medicinal product, i.e. "any ready-prepared medicinal product placed on the market under a special name and in a special pack", in accordance with the definition given in Article 1 of that Directive. The product therefore meets this second condition if the proprietary medicinal product containing it has been granted the authorization concerned.

35. It occurs very often that one and the same product is successfully granted several authorizations to be placed on the market, namely each time a modification is made affecting the pharmaceutical form, dose, composition, indications, etc. In such a case, only the first authorization for the product to be placed on the market in the Member State in which the application is presented is taken into account for the purposes of the proposal for a Regulation, in particular for calculating the period of six months which the holder of the basic patent has to submit an application for a certificate. Furthermore, if the first authorization given is also the first authorization to place the product on the market in the Community, it serves as the only reference for all of the Member States for the purposes of calculating the duration of each of the certificates granted in each of the Member States for the same product (see Article 8).

36. Lastly, the product must not have been the subject of a certificate in the Member State concerned. The certificate is designed to encourage research into new medicinal products so that the duration of protection it affords, together with the effective duration of protection by patent, is sufficient to enable the investments made in the research to be recovered. However, it would not be acceptable, in view of the balance required between the interests concerned, for this total duration of protection for one and the same medicinal product to be exceeded. This might nevertheless be the case if one and the same product were able to be the subject of several successive certificates.

This calls for a strict definition of the product within the meaning of Article 2. If a certificate has already been granted for the active ingredient itself, a new certificate may not be granted for one and the same active ingredient whatever minor changes may have been made regarding other features of the medicinal product (use of a different salt, different excipients, different pharmaceutical presentation, etc.).

In conclusion, it should be noted that, although one and the same product may be the subject of several patents and several authorizations to be placed on the market in one and the same Member State, the supplementary protection certificate will only be granted for that product on the basis of a single patent and a single authorization to be placed on the market, namely the first chronologically given in the State concerned (the first authorization in the Community being taken only to calculate a uniform duration of different certificates for one and the same product).

37. Lastly, Article 3 specifies that the certificate is granted to the holder of the basic patent. Any decision as to the advisability of applying for a certificate must be left to the holder of the basic patent who alone is able to decide whether this is advisable.

Article 4

38. The supplementary protection certificate is a protection certificate sui generis inasmuch as it is linked to both an authorization to place the product on the market (the first chronologically given in the State concerned) and to a previous patent (the basic patent). This is already evident from the conditions for obtaining the certificate, which require both that the basic patent is in force and that the authorization is valid, failing which the certificate is void.

39. The delimitation of the subject protected by the certificate also illustrates this duality since the protection given by the certificate is limited in two ways.

It is thus often the case in the chemical and pharmaceutical field that a patent protects a series of products based on the same formula. However, only some of these products will subsequently be developed and possibly only one may be put on the market. In such a case, the certificate will only protect the product covered by the authorization and not all of the products protected by the patent.

At the same time, the product authorized will itself be limited by the subject protected by the basic patent. If the basic patent protects a compound x, where the product authorized consists of a combination of compound x and another active ingredient only compound x will be protected by the certificate.

Furthermore, the certificate will protect only the product covered by the authorization, namely the product within the strict meaning of Article 2.

40. Lastly, the fact that the certificate is based on both the basic patent and the authorization can also be seen in the link between the protection given and the use of the product.[1]

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1 In the French text, the term "utilisation" is used for both the patent system and the authorization system, the terms in French normally being "application" and "indication" respectively. In the English text, the same term "uses" is used for both systems.

In this respect, a new product patent normally gives the product absolute protection so that any use of the patented product, even for non-patented applications, constitutes an infringement, i.e. it protects all possible uses that the product may have.

The certificate does not given such protection. On the one hand, the link with the authorization system means protection of the product covered by the first authorization, while limiting it to the uses of the product successively authorized prior to the expiry of the basic patent (research laboratories frequently develop new uses of the same product, which are the subject of new marketing authorizations). The marketing authorization is actually given several years after the filing of the patent, during which time the medicinal product undergoes multiple tests for one or more very specific uses. In view of this, it would seem to be logical to protect it, by means of the certificate, for all uses which have been the subject of authorizations.

41. Furthermore, only uses in the pharmaceutical field as defined in Directive 65/65/EEC and 81/851/EEC come under the protection of the certificate (authorized use of the product as a herbicide, for example, would not be protected under the certificate).

42. On the other hand, the protection granted by the certificate is limited by that of the basic patent. In the case of a product patent, the limitation under the patent will not apply since this type of patent protects all possible uses of the product. However, in the case of an application patent, the certificate will only be able to protect the use or uses claimed in the patent, provided that they were authorized prior to the expiry of the basic patent.

## Article 5

43. The effects of the certificate on the subject to which it refers as described in Article 4 are the same as those of the basic patent.

The patent system has hitherto constituted the best tool to encourage research. It is therefore not surprising, in view of the objective of this Regulation, that the certificate grants the same rights, subject to the same limitations.

44. Consequently, in the case of a basic patent covering a product, the rights granted by the certificate will be the same as those granted by the patent, but limited to any use of the product authorized prior to the expiry of the patent.

Similarly, in the case of a basic patent covering a use of the product, the right granted by the certificate will be the same as those granted by the patent, but limited to the use covered by the patent and authorized prior to the expiry of the patent.

Lastly, in the case of a basic patent covering a process for obtaining the product, the rights granted by the certificate will be the same as those granted by the patent, but limited to the procedure used to obtain the authorized product. The rights granted by the certificate will be extended to the product if the law applicable to the basic product lays down that the protection of a process for obtaining a product extends to the product directly obtained by that process.

45. The certificate is lastly subject to the same restrictions as the basic patent. Restrictions on private acts for non-commercial purposes, restrictions on acts for experimental purposes relating to the subject of the certificate and restrictions on obligatory licences relating to the subject of the certificate are some of the possible restrictions on the rights granted by the certificate if these are also included in the basic patent.

## Article 6

46. This Article concerns the time during which the application for the certificate must be submitted and the content of the application.

With regard to the time, a period of six months is provided from the date on which the first authorization to place the product on the market in the State concerned was obtained. This solution takes particular account of the interests involved; those of the patent holder who, after having applied for the certificate, may, if he so wishes, forego the certificate if his product proves to be unsuccessful on the market; and those of third parties who have every interest in knowing as early as possible whether or not the product concerned will be protected by a certificate once the basic patent has expired.

Furthermore, it need not be feared that applications for a certificate will be routinely and systematically filed each time authorization to place a product on the market is given, since the conditions laid down in Article 3 for obtaining the certificate are strict and allow only one certificate per product corresponding to the first authorization given in the State concerned.

47. It may happen that authorization is given before the basic patent is granted, in particular in the field of genetic engineering in which applications may be left pending for quite a long time. In such cases, the period begins on the date on which the patent is given.

48. The following comments should be made with regard to the content of the application. Few documents are required. Apart from the request itself, a copy of the first authorization to place the product on the market in the State concerned is required as this enables the product to be identified. If this authorization is not also the first authorization to place the product on the Community market, a copy of the latter also has to be attached since the duration of the certificate will be calculated, in all Member States in which a certificate is applied for, by reference to this criterion alone.

Information enabling the basic patent to be identified must also be provided.

The authority empowered to grant the certificate will have to verify that the authorization(s) and the patent refer to one and the same product.

Lastly, the application must contain a summary of the pharmacological properties of the product. These are the properties which enable it to be characterized as a medicinal product and, consequently, which help to provide a better description of the product as a medicinal product. It is also a requirement that is easy to meet once all the experiments on the product have been carried out.

Article 7

49. The application for a certificate must be submitted to the patent offices of the Member States. The office responsible for each application for a certificate is that in the State which has delivered or on whose behalf was delivered a basic patent and in which the first authorization for that State was obtained.

For one and the same medicinal product patented and authorized to be placed on the market in several Member States, as many applications for certificates must be submitted to the corresponding patents offices.

The application for a certificate may be subject to the payment of a tax to the patents office concerned to cover expenditure incurred in dealing with the application.

The application for a certificate must lastly be published by the patents office. This is to ensure that third parties are informed as soon as possible.

Article 8

50. The duration of protection granted by the certificate is established on the basis of several factors.

First, the duration must be sufficiently long to meet the objectives of the proposal. In this respect, it is necessary to avoid discriminating against pharmaceutical research and therefore to subject it to conditions similar to those which would obtain if the medicinal products were not subject to prior authorization to be placed on the market.

The duration of the certificate covering one and the same medicinal product must be the same throughout the Community in order to facilitate the functioning of a genuine Community market.

Account also has to be taken of the laws benefitting competitive firms in their own markets in order to put all of European industry on a similar footing.

However, it is also essential to take account of other aims of health policy and therefore to prevent the duration of protection of the medicinal products from becoming a barrier to them.

Lastly, the system must be kept simple, while allowing for a certain degree of balance between all of the interests involved.

51. The Commission therefore proposes to calculate the duration of the protection of the certificate on the basis of the protection period "lost" under the patent, i.e. the period between the date on which the patent application is filed and the date on which the first authorization to place the product on the market in the Community is obtained.

As the authorization dates for one and the same medicinal product differ from one Member State to another, the later an authorization is given in a Member State, the shorter the period of effective protection will be there. The Commission's policy on authorizations should nevertheless reduce the gaps between Member States and therefore virtually level out the effective durations of protection afforded to medicinal products.

To put medicinal products on a footing similar to that which would obtain in the absence of authorization means placing them on the terms that obtain in other sectors of technology not subject to authorization. The Commission puts the average period from the date on which the patent application is filed to the date on which it is placed on the market at four years. The duration of protection under the certificate thus calculated (the period "lost" less four years) takes effect on the day following the end of the lawful term of the basic patent.

52. It should be stressed that, if the effective period remaining under the basic patent, i.e. from obtaining the authorization to the end of the patent, is added to the duration of protection under the certificate - the period lost less four years - a total effective period of protection for the medicinal product concerned of sixteen years is obtained, below which, in the Commission's view, the objectives of this proposal for a Regulation will not be attained.

53. Lastly, it should be pointed out that the proposal also provides for a final date after which the medicinal product enters the public domain. The duration of the certificate may not exceed 10 years from the date on which it takes effect.

The simplicity of the system means that it is not possible to take account of certain factors, such as the diligence that the innovating firm has shown throughout all the tests required to obtain the authorization. The proposal compensates for this shortcoming by restricting the certificate in cases in which authorization was obtained very late. For example, if the authorization was obtained eighteen years after the application for the corresponding patent was filed, the duration of the certificate is not fourteen years (eighteen minus four) but ten years, after which there is no further protection.

Article 9

54. This Article refers to the conditions governing the grant of the certificate or rejection of the application and publication.

The only particular comment called for is to underscore the simplicity of the procedure; no particular difficulties should arise in its application.

All patent offices must in particular be able to verify the conditions referred to in Article 3 under which the certificate is obtained. Contacts may, if necessary, be provided for between the patent office and the authority responsible for authorizing the product to be placed on the market, if this is considered necessary for the purposes of the procedure.

Article 10

55. This Article states that the Member States may provide that renewal of the certificate will be subject to the payment of a fee. It will be for the Member States to establish the amount if they decide to introduce such fees, failure of which to pay would cause the certificate to lapse

Article 11

56. The proposal for a Regulation lays down three grounds for nullity of the certificate.

1) The certificate is void if the conditions for obtaining the certificate as laid down in Article 3 have not been complied with. This will in particular concern cases in which the authorization to place the product on the market was not valid

or was not the first in the Member State concerned, cases in which the basic patent was no longer in force when the certificate was applied for and, lastly, cases in which one and the same product was the subject of several certificates in the same Member State, in which case only the certificate granted in respect of the first authorization to place the product on the market in the State concerned will be valid.

2) The certificate is void if the basic patent is not valid when its lawful term expires. Where renewal of a patent until its term expires is indicative of the value of the product it protects, this ground for nullity will play an important selective role.

Furthermore, the exclusive protection granted by the certificate over a given period is not lawful unless the product concerned meets not only the specific conditions for obtaining the certificate (Article 3), but also the criteria of patentability for grant of the basic patent.

It is therefore necessary to specify that the certificate is void if *the* basic patent or at least that part of the basic patent that corresponds to the product covered by the certificate has been revoked. It is therefore necessary to specify expressly that an application for revocation of the basic patent, with a view to the revocation of the certificate, may be submitted even after the lawful term of the basic patent has expired.

3) The certificate is also void if the subject that it protects is not covered by the basic patent. The aim is to prevent a given product not protected by a patent from enjoying the exclusive protection of a certificate without having fulfilled the conditions and obligations specific to the patent system.

This ground for nullity is therefore based on the same principle as the previous ground. It remains to be pointed out that, if the subject of the certificate is only partially covered by the basic patent, the declaration of nullity of the certificate may take the form of a corresponding limitation of the certificate, this being in accordance with the principle of proportionality.

57. Lastly, the Article specifies that any person may request a declaration of nullity of the certificate from the authority which granted it, i.e. the relevant patent office. The decision of the office will be subject to appeal, as provided for in Article 12.

Article 12

58. This Article provides that a decision to reject an application and any decision of a patent office to which an application for a certificate was made to annul the certificate are open to the same appeals as provided for in national law against similar decisions regarding patents. This is an essential legal guarantee, claims under which are subject to national patent law of the State in which the certificate was granted.

59. The same possibility of appeal shall apply to decisions in respect of the grant of a certificate, for reasons of invalidity of the granting decision, for example, a defective procedure, lack of competence of the granting authority, etc. The certificate itself may indeed be annulled under the provisions of Article 11, and the annulment itself is open to appeal under the provisions of Article 12.

Article 13

60. The aim of this Article is to lay down transitional arrangements, a particularly important and sensitive part of the proposal. The Commission takes the view that certain criteria have to be complied with in order to arrive at an appropriate solution.

A balancing of all the interests at stake is fundamental to achieve an acceptable solution. In this respect, the aim is neither to cover all products already being marketed nor to exclude them totally.

The proposed solution must avoid any distortion to the system for granting authorization to place a product on the market that might cause firms to delay submitting an application for such authorization.

Lastly, the solution must be free of uncertainty in order to enable companies to plan ahead.

61. In the light of these criteria, the Commission proposes:

(a) to apply the proposal for a Regulation to all products protected by a patent in force which have not yet received authorization to be placed on the market;

(b) to apply it also to all products authorized after 1 January 1984 and the patents for which expire after 1 July 1992.

Laying down specific dates avoids the uncertainty caused by any reference to the date of entry into force of the proposal. With regard to the choice of dates, authorization since 1 January 1984 should enable European industry to close the gap between them and their US competitors, who have had restoration of pharmaceutical patents since 1984. Furthermore, by setting a patent expiry date of post 1 January 1992, a product for which a patent was filed in 1972 will not be able to be granted a certificate unless the corresponding authorization was given more than twelve years after it was filed (after 1984), i.e. after a period representing the average reference period in the proposal for a Directive, which was calculated on the basis of existing statistics.

c) to limit the maximum duration of protection given by a certificate to five years for products authorized since 1984. This is a reduction to half of the normal time provided for in the proposal.

32

# Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products

*(COM(90) 101 final — SYN 255)*

*(Submitted by the Commission on 3 April 1990)*

(90/C 114/11)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission,

In cooperation with the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas pharmaceutical research plays a decisive role in the continuing improvement in public health;

Whereas medicinal products that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research;

Whereas at the moment the period that elapses between the discovery of a new medicinal product, at which time the application for a corresponding patent is filed, and authorization to place the medicinal product on the market is continually increasing, thereby making the period of effective protection under the patent insufficient to cover the investment put into the research;

Whereas this lack of protection penalizes pharmaceutical research;

Whereas the current situation is creating the risk of European research centres relocating to countries that already offer greater protection;

Whereas a uniform solution at Community level should be provided for, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the Community and thus directly to affect the establishment and the functioning of the internal market;

Whereas the creation of a supplementary protection certificate granted, under the same conditions, by each of the Member States at the request of the holder of a national or European patent relating to a medicinal product for which valid marketing authorization has been granted by the State concerned is necessary; whereas the legislative form of a Regulation is therefore the most appropriate;

Whereas the duration of the protection granted by the new certificate should be determined to enable a medicinal product to be given the effective protection it would have if it were not subject to authorization to be placed on the market; whereas, for this purpose, the holder of both a patent and a certificate should be able to enjoy 16 years of exclusivity from the time the product is first placed on the market in the Community;

Whereas all the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector must nevertheless be taken into account; whereas, for this purpose, the certificate cannot be granted for a period exceeding 10 years; whereas the protection granted should furthermore be strictly confined to the product covered by the marketing authorization;

Whereas a fair balance should also be struck with regard to the determination of the transitional arrangements; whereas such arrangements should enable the Community pharmaceutical industry to catch up to some extent with its main competitors who, for a number of years, have been covered by laws assuring them of more adequate protection, while making sure that the arrangements do not compromise the achievement of other legitimate objectives concerning the health policies pursued at both national and Community level,

HAS ADOPTED THIS REGULATION:

*Article 1*

**Definitions**

For the purposes of this Regulation,

(a) *Product* means any active substance or combination of substances presented for treating or preventing disease in human beings or animals and any active substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;

(b) *Product protected by a patent* means any product as defined in (a) protected by a patent covering the product itself, or a process to obtain the product, or an application of the product or a combination of substances containing the product;

(c) *Certificate* means the supplementary protection certificate.

*Article 2*

**Scope**

Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market, to an administrative authorization procedure as laid down in Council Directive 65/65/EEC (1) or Council Directive 81/851/EEC (2) may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.

*Article 3*

**Conditions for obtaining a certificate**

1. A certificate shall be granted if, in the Member State in which the application referred to in Article 6 is submitted and at the date of that application,

(a) the product is protected by a patent in force, hereinafter called *basic patent;*

(b) a valid authorization to place the product on the market has been granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC, as appropriate;

(c) the product has not already been the subject of a certificate;

(d) the authorization referred to in (b) is the first authorization to place the product on the market.

2. The certificate shall be granted to the holder of the basic patent.

*Article 4*

**Subject matter of protection**

Within the limit of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorization to place it on the market and for any authorized use of the product before the expiry of the basic patent and as provided for in Directives 65/65/EEC or 81/851/EEC.

*Article 5*

**Effects of the certificate**

Subject to the provisions of Article 4, the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations.

*Article 6*

**Application for a certificate**

1. The application for a certificate shall be lodged within six months of the date on which the authorization to place the product on the market referred to in Article 3 (1) (b) was granted.

2. Notwithstanding the provision of paragraph 1, where the authorization to place the product on the market is granted before the basic patent is granted, the application for a certificate shall be lodged within six months of the date on which the patent is granted.

3. The application for a certificate shall contain:

(a) a request for the grant of a certificate;

(b) a copy of the authorization to place the product on the market, as referred to in Article 3 (1) (b), in which the product is identified;

(c) if the authorization referred to in (b) is not the first authorization for placing the product on the market in the Community, information regarding the date on which the first such authorization was granted, the identity of the product thus authorized, the legal provision under which the authorization procedure took place and a copy of the authorization;

(d) identification of the basic patent;

(e) information regarding the pharmocological properties of the product in the form of a summary as provided for in particular in Article 4a (4) of Directive 65/65/EEC.

*Article 7*

**Lodging of an application for a certificate**

1. The application for a certificate shall be lodged with the central industrial property office of the Member State which granted the basic patent or on whose behalf it was granted and in which authorization to place the product on the market as referred to in Article 3 (1) (b) was obtained.

2. Member States may require that the application for a certificate shall be subject to payment of a fee imposed by the authority referred to in paragraph 1.

(1) OJ No 22, 9. 2. 1965, p. 369/65.

(2) OJ No L 317, 6. 11. 1981, p. 1.

3. The application for a certificate shall be published by the authority referred to in paragraph 1.

*Article 8*

**Duration of the certificate**

1. The certificate shall take effect on the day following the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the Community, as referred to in Article 6 (3) (c), reduced by a period of four years.

2. Notwithstanding paragraph 1, the duration of the certificate may not exceed 10 years from the date on which it takes effect.

*Article 9*

**Grant of the certificate or rejection of the application**

1. The authority referred to in Article 7 (1) shall reject the application for a certificate if the application or the product to which it relates does not meet the conditions laid down in this Regulation.

2. Where the application for a certificate and the product to which it relates meet the conditions laid down in this Regulation, the authority referred to in Article 7 (1) shall grant the certificate.

3. The fact that a certificate has been granted shall be published by the authority referred to in Article 7 (1), giving in particular the following details:

(a) name and address of the holder of the certificate;

(b) number of the basic patent;

(c) identity of the product covered by the certificate;

(d) duration of the certificate;

(e) a summary of the pharmacological properties as referred to in Article 6 (3) (e).

*Article 10*

**Renewal fees**

1. Member States may require that the certificate shall be subject to the payment of renewal fees imposed by the authority referred to in Article 7 (1).

2. The failure to pay such fees will result in the lapse of the certificate.

*Article 11*

**Grounds for nullity of the certificate**

1. The certificate shall be void if:

(a) it was granted contrary to the provisions of Article 3;

(b) the basic patent is no longer in force when its lawful term expires;

(c) the subject of the certificate is not covered by a basic patent.

2. For the purposes of paragraph 1 (b), an application for a declaration of nullity of the basic patent may be presented before the lawful term of the patent expires.

3. In the case referred to in paragraph 1 (c), if the subject of the certificate is only partially covered by the basic patent, the declaration of nullity shall take the form of a corresponding limitation of the certificate.

4. Any person may request a declaration of nullity of the certificate from the authority which granted it.

*Article 12*

**Appeals**

The decisions of the authority referred to in Article 7 (1) taken under Articles 9 (2) and 11 shall be open to the same appeals as those provided for in national law against similar decisions taken in respect of national patents.

The same shall apply in respect of decisions taken pursuant to Article 9 (2) which are alleged to be invalid on grounds other than those referred to in Article 11.

**TRANSITIONAL PROVISION**

*Article 13*

1. Any product which, on the date on which this Regulation enters into force, is protected by a valid patent and for which authorization to place it on the market in the Community has not yet been obtained may benefit from the application of this Regulation.

2. Any product which, on the date on which this Regulation enters into force, is protected by a valid patent which expires after 1 July 1992 and for which a first authorization to place it on the market in the Community was obtained after 1 January 1984 may also

be granted a certificate, the duration of which may not, however, exceed five years.

3. An application for a certificate, made under paragraph 2, shall be submitted within six months of the date on which this Regulation enters into force.

FINAL PROVISIONS

*Article 14*

**Implementing Regulation**

1. Detailed rules for the application of this Regulation, in so far as they are necessary, shall be laid down by an implementing Regulation.

2. The implementing Regulation shall be adopted by the Commission.

*Articles 15*

**Entry into force**

This Regulation shall enter into force 60 days after its publication in the *Official Journal of the European Communities.*

This Regulation shall be binding in its entirety and directly applicable in all Member States.

V.

## FICHE D'IMPACT SUR LA COMPETITIVITE ET L'EMPLOI

**I. Quelle est la justification principale de la mesure ?**

- Promotion de la recherche pharmaceutique.
- Amélioration de la protection de la santé publique.
- Renforcement de la compétitivité de l'industrie européenne sur le marché mondial.
- Bon fonctionnement du marché intérieur.

**II. Caractéristiques des entreprises concernées.**

La proposition concerne des firmes pharmaceutiques.
Vu le coût élevé du développement des nouveaux produits, les firmes pharmaceutiques sont souvent de grandes entreprises (multinationales ou nationales). Il existe néanmoins un certain nombre de petites et moyennes entreprises à vocation nationale, qui font également de la recherche, notamment dans le domaine de la biotechnologie, où il n'est pas toujours nécessaire de disposer de grands moyens.

**III. Quelles sont les obligations imposées directement aux entreprises ?**

Se conformer à la procédure prévue pour l'obtention d'un certificat complémentaire de protection.

**IV. Quelles sont les obligations susceptibles d'être imposées indirectement aux entreprises via les autorités locales ?**

Aucune.

**V. Y a-t-il des mesures spéciales pour les PME ?**

Non.

VI. Quel est l'effet prévisible

a) sur la compétitivité des entreprises ?

Un des objectifs poursuivis par la mesure concernée est précisément de renforcer la compétitivité des entreprises européennes face à leurs concurrents étrangers (USA), Japon).

b) sur l'emploi ?

Le renforcement de la compétitivité devrait se traduire par un effet plutôt positif sur l'emploi.

VII. Les partenaires sociaux ont-ils été consultés sur cette proposition ?

Ont été consultées :

- les associations de l'industrie pharmaceutique et chimique,
- les associations de consommateurs,
- les chambres de commerce et d'industrie.

VI.

## FICHE FINANCIERE

La présente proposition n'a pas d'effet sur le budget communautaire. Elle sera menée à bien grâce aux ressources existantes à la DG III.