



EGA Position Paper

***Data Exclusivity:
A Major Obstacle to Innovation and Competition
in the EU Pharmaceutical Sector***

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The EGA represents over 400 companies in Europe
dedicated to the production and supply of affordable generic medicines.

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EGA Position Paper

Data Exclusivity: A Major Obstacle to Innovation and Competition in the EU Pharmaceutical Sector

1. Summary

Recent demands by originator companies to harmonise data exclusivity at 10 years and to introduce data exclusivity for medicinal product variations seriously threaten EU Member States' efforts to promote competition through the increased use of generic medicines.

Arguments for extending data exclusivity provisions have four main faults:

- They ignore the fact that patents are already available for new usages and new formulations i.e. originator companies are requesting superfluous protection by means of data exclusivity for areas already protected.
- They ignore the fact that the EU already has the highest level of patent protection and data exclusivity provisions in the world.
- They fail to make a causal link between data exclusivity and encouraging innovation.
- They ignore the fact that such extensions would make the EU's Mutual Recognition Procedure unworkable for generic medicinal products.

Where a pharmaceutical product is innovative, patent law in the EU already provides for market protection for up to 15 years. Furthermore, the arguments being used to gain increased data exclusivity today are the same used to successfully gain patent extensions (i.e. SPCs) in 1992. Having obtained this extra market protection, the same reasons cannot be used to extend market protection once again. It should also be stressed that widening data exclusivity provisions would undermine genuine innovation in the EU, since it would encourage originator companies to focus their activities on product changes, rather than focus on developing new innovative and beneficial products. As for the EU generic medicines industry, there is generally no interest by companies in having their own formulation changes protected by means of data exclusivity. Generic companies would rather protect any innovative development they made by patenting the invention.

Finally, there is a strong argument that regulatory legislation should only be concerned with safety, efficacy and quality of products and not with issues of market protection and intellectual property. This is a view already held by some authorities in the EU.

Taking all these points into consideration, the EGA proposes that only certain non-patented NCEs be eligible for exclusivity and that the period in all such cases be limited to 6 years – the period already operated by half of the EU Member States. An institution, other than the regulatory authorities or EMEA, should operate the new system.

2. Data Exclusivity: Why it Exists and How it Works

The EU's data exclusivity lawsⁱ, as provided for in Directive 65/65EEC (amended by Directive 87/21/EEC), give the first market authorisation holder of a New Chemical Entity (NCE) a guaranteed period of market exclusivity.

This is done by way of the Regulatory Authorities only accepting an application for generic medicines after the expiry of the 6- or 10-year periodⁱⁱ. The data exclusivity provision effectively prevents the Regulatory Authorities from checking whether a generic applicant is "essentially similar" to the originator product. After this given period, Regulatory Authorities are able (internally) to refer to the data of Part III and IV of the originator file in order to assess the generic application for safety and efficacy. Data exclusivity is therefore a misleading term; a more appropriate term is market exclusivity.

Four points need to be stressed concerning data exclusivity provisions in the EU:

1. The 10-year period, as operated in the Centralised Procedure and by 7 Member States nationally, was created at a time when there were no patents for biotech products. This data exclusivity period therefore provided a form of market protection for these products in the absence of patents, which was particularly important to those Member States with developing biotech industries. Patents now exist for biotech products.
2. Half of EU countries actually operate a 6-year period of data exclusivity not a 10-year period, and in three cases the period must not extend beyond the patent period. Moreover, Iceland and Norway (which use the MRP) and most countries seeking EU accession are expected to opt for a 6-year periodⁱⁱⁱ.
3. It is evident from the text of the preamble of Council Directive 87/21 EEC dated December 22, 1986 that the main aim of data exclusivity was not to hinder the registration of generic medicines but to enable the registration of abridged applications in order to avoid repetitive testing on humans and animals without overriding cause, whilst at same time not putting real innovation at a disadvantage.
4. Finally, even after this period, commercially sensitive data is still not disclosed to third parties i.e. generic companies or the public at large. Generic companies for their part do not use the data of the originator but generate their own data (i.e. expert reports referring to official publications, Pharmaceutical Data and Bio-equivalence studies).

3. Increased Level of Intellectual Property Protection Makes Data Exclusivity Unnecessary

Since data exclusivity provisions were introduced in the EU in 1987, there has in fact been a fundamental increase in the level of intellectual property protection for

pharmaceutical products, which makes data exclusivity unnecessary as a form of market protection. Consequently, the EU now has the highest level of patent protection in the world, partly resulting from the following key legislations:

- Patents are now available for biotech products^{iv};
- 15/17-year product/process patents have been replaced by 20-year product patents;
- Market protection periods for 20-year patents on medicinal products are increased by further maximum period of 5 years by the Supplementary Protection Certificate Regulation (1768/92/EEC) i.e. EU law *already* compensates for the time and cost involved in developing data for registration^v; and
- Patents are increasingly granted for new uses, indications (“Swiss claims”), dosages and changes in formulations. Indeed, proposals have been adopted at the Diplomatic Conference reviewing the European Patent Convention, making such usage claims even more obtainable^{vi}.

When the debate was launched to introduce full product patent protection and then Supplementary Protection Certificates (SPCs), the basic argument used was that the most time consuming and expensive parts of drug development were clinical studies (phases I-IV). Having obtained increased patent protection the same argument cannot be used again today to demand extending data exclusivity provisions.

Moreover, as is common knowledge, most pharmaceutical inventions are covered by a multitude of patents, i.e. there is hardly ever just one patent for a pharmaceutical product, thereby protecting original pharmaceuticals even more. The most prevalent patents are on:

- Substance
- Compound
- Formulation
- Usage
- Process
- Mechanism of action
- Intermediates.

For example, over 26 types of patents, covering methods, process, intermediates, designs and formulations cover SmithKline Beecham's Tagamet (cimetidine).

The high level of IP protection and wide application of patents simply make data exclusivity provisions now unnecessary.

4. Data Exclusivity and Innovation: A False Link

Arguments for increased data exclusivity provisions fail to demonstrate why data exclusivity provisions, rather than patents, should be used to promote or reward innovation. With the availability of patent protection, data exclusivity can only be

intended to unfairly protect investment. Like in all other industries, rewards for product improvement should be the result of a normal market process and should not result from artificial legal protection.

In assessing the future of data exclusivity provision, it is critical that policy makers consider the following six points:

1. **Data exclusivity protects non-innovation.** If product variations or new uses cannot gain patent protection because they cannot demonstrate novelty and inventive step, it is simply wrong that they should be able to obtain market protection through the backdoor by gaining data exclusivity.
2. **Data exclusivity periods are granted without having to demonstrate any of the basic principles of patent law**, which seek to ensure the development of innovation i.e.
 - Demonstration of novelty and inventive step;
 - Publication of information to further prospect's of future innovation; and
 - Right of appeal by third parties against an incorrect decision to grant exclusive rights.
3. **There is no link between long periods of data exclusivity and promoting innovation.** The European Union already has one of the longest and most restrictive periods of data exclusivity in the world but is still *less* successful in the rate of development of new innovative products than the USA, which operates a 5/3-year data exclusivity period. (For comparisons see footnote below ^{vii}).
4. **Granting data exclusivity for variations would discourage true innovation** since companies would be encouraged to invest time and resources into developing minor changes to existing products to maximise profits by preventing generic competition, rather than to developing innovative products. At present even under existing data exclusivity laws too much focus is given by originator companies to making product changes than to real innovation.
5. **Under EU procedures product variations are often approved by means of a line extension, and not by way of a full application.** The subsequent application benefits from using the information submitted for the original application. Therefore there is no case for granting data exclusivity in such situations.
6. **Clinical trials are themselves often co-subsidised by public bodies or research foundations** carried out by doctors and involve sick volunteers. It is hard to justify that the data gathered solely belongs to the company that developed and is marketing the pharmaceutical product.

For all these reasons, data exclusivity provisions are clearly not compatible with the EU's explicit policies of encouraging innovation, stimulating fair competition and promoting public health. As for the EU generic medicines industry, there is generally no interest by

companies in having their own formulation changes protected by means of data exclusivity. Generic companies would rather protect any innovative development they made by patenting the invention. The originator companies' argument that generic companies would benefit from data exclusivity is not substantiated and seems to be more of a tactic to gain data exclusivity for variations to *their* own original product.

5. Expanding Data Exclusivity Would Make the EU Mutual Recognition Procedure Unworkable for Generic Medicines

The operation of the current data exclusivity laws is already operating in conflict with the EU's objectives in promoting the harmonisation of the Single Market. Several problems exist:

- The presence of 10-year data exclusivity provisions in certain Member States as opposed to a harmonised 6-year period has distorted the EU market, making the Mutual Recognition Procedure (MRP) extremely difficult to operate particularly for the introduction of new generic medicines. Harmonisation of SmPC's (Summary of Product Characteristics) between EU Member States is key to the success of the Mutual Recognition Procedure. This is currently problematic, as different Health Authorities have accepted different SmPC's for the same (originator company) medicinal product. If extra exclusivity is applied to anything other than the first authorisation, each change of indication to the originator will give a different SmPC and each SmPC a different data exclusivity period. This will prevent the registration, especially via MRP, of generic products, as they cannot ever be approved with the same current SmPC as an originator. The MRP will be unfeasible for the same generic product across the EU, and there would be no way of obtaining a marketing authorisation in more than one Member State. This will clearly result in an unacceptable partition of the EU market.
- Revocation of a licence by an originator company just before expiration of data exclusivity can lead to the blocking of abridged applications, on the basis that the regulatory authorities no longer have access to information on the reference product with which to demonstrate essential similarity. The problem is particularly acute where a 10-year period of data exclusivity operates, as this provides the originator company with a long period of protection during which it can generate variants to replace its existing product. The present law, which only allows data exclusivity to be related to the first application of a product and not to subsequent changes to indications, dosages and schedules, is vital to preventing widespread abuse of the data exclusivity laws.

Extending data exclusivity provisions would therefore increase the regulatory hurdles against generic entry rather than seek to improve entry. This is in direct conflict with the European Commission's own stated policy that the regulatory system should operate in such away "that consumers have access to lower priced generics as soon as possible after patent protection of the original product expires"^{viii}.

Furthermore, regulatory authorities should not be required to deal with data exclusivity, which is effectively a market protection or quasi-intellectual property issue. There is clearly a strong argument that regulatory legislation should only be concerned with the safety, efficacy and quality of medicinal products. This point is already shared by certain regulatory authorities, according to the findings of the Cameron McKenna/Andersen Consulting report on the *Evaluation of the Operation of Community Procedures for the Authorisation of Medicinal Products* (November 2000)^{ix}.

6. TRIPS Does not Impact on EU Data Exclusivity

Originator companies have also attempted to use Article 39.3 of TRIPS to support their case for strengthening data exclusivity provisions in the EU. However, since Article 39.3 does not relate to data exclusivity, there is in effect no impact of TRIPS on EU laws.^x

In addition, arguments have been made that data exclusivity laws, which prevent the exclusivity periods from extending beyond the period of a patent (as are operated in 3 EU Member States), are incompatible with TRIPS.

However three points should be noted:

1. Article 39.3 does not grant data exclusivity rights as operated in the EU but requires the protection of undisclosed information against unfair commercial use. The principal affect of Article 39.3 is to prevent clinical data from being accessible to third parties, not to create market exclusivity right as EU data exclusivity laws provide.
2. Article 39.3 provides no fixed period for the protection of the information.
3. Article 39.3 makes reference only to NCEs.

7. Data Exclusivity for Certain (Non-patented) New Chemical Entities

In general there is very little argument for maintaing any form of data exclusivity.

However, the European generic industry accepts that there may be a case for providing data exclusivity, or more appropriately market exclusivity, for certain New Chemical Entities, which have neither a product patent nor a process patent but for which registration in the EU required considerable effort.

In such cases the 6-year exclusivity period could be granted but only if the following four conditions are met:

1. That a process patent or product patent does not exist for the NCE either within the EU or in third countries.^{xi}

2. That no application for a process or product patent was previously applied for and subsequently rejected on the basis of failing to meet requirements of innovation.
3. That the generation of the data required for submission to the EU involved considerable efforts and expense to the applicant.
4. That any grants, tax incentives or other cost recovery provisions received by the sponsor either within the EU or third countries should be taken into account in establishing the condition to be met in point 3 above.

Granting a 6-year period - as opposed to a longer period - is logical for the following reasons:

- A 6-year data exclusivity period is already operated by half of the EU countries and by Iceland and Norway. It is also the period most likely to be adopted by countries seeking EU accession.
- Since a 10-year market exclusivity period is granted to orphan medicinal products which by their nature are not expected “to generate sufficient return to justify the necessary investment”, it is logical that a period equal to around half this period be given to products which are expected to generate profitable returns on investment. Indeed, under the orphan drug legislation, at the end of the fifth year the market exclusivity period will be reduced to 6 years, if it is established, that the criteria met for orphan drug status are no longer met.
- 5-year data exclusivity periods operate outside the EU.

However, it would be more appropriate that such an exclusivity right was obtained from and administered by an institution other than the regulatory authority, since the regulatory authority should only be responsible for assessing the safety, efficacy and quality of medicinal products.

8. Freedom of Information

On expiry of any data exclusivity period full details should be made public. This will ensure that the public, having rewarded the innovator with an exclusivity period, is able to utilise the data as necessary without difficulty.

9. Conclusion

The correct way of ensuring genuine innovation is through a balanced system of patent protection.

In view of the substantially increased levels of IP protection for pharmaceutical products in the EU and the availability of patents on uses and formulations, data exclusivity provisions are no longer necessary nor justified for protecting pharmaceutical innovation.

Moreover, there is no link between long periods of data exclusivity and increased innovation. In fact, extending data exclusivity to product variants would actually discourage innovation and cause a major block in competition within the off-patent sector. This would be in direct conflict with both the EU Member States' efforts to increase the use of generic medicines, and the European Commission's declared objective, that the EU regulatory system should operate to ensure that consumers have access to lower priced generics as soon as the patent protection of the original product expires.

Finally, there is a strong argument that regulatory legislation should only be concerned with safety, efficacy and quality of products and not with issues of market protection and intellectual property.

For all these reasons, the EGA proposes that only certain non-patented NCEs be eligible for exclusivity and that the period in all such cases be limited to 6 years – the period already operated by half of the EU Member States. It should be considered whether an institution, separate from the regulatory authorities or EMEA, could operate this new system of exclusivity.

ⁱ Under EU law data exclusivity is granted to cover the information submitted for the first authorisation of a medical product based on a full dossier i.e. the Chemical, Pharmaceutical and Biological Documentation, Toxicological and Pharmacological Tests and Clinical Documentation required for the approval of a new medical product. Additional protection is not granted for any new data relating to any subsequent variations such as changes in indications, dosages, and strengths.

ⁱⁱ Data exclusivity is granted to products registered through national procedures and Mutual Recognition Procedure by way of Article 4.8.a iii of Directive 65/65EEC as amended by Directive 87/21/EEC. In the case of national procedures there is no harmonised period. Member States are entitled to operate either a 6-year or 10-year data protection period.

ⁱⁱⁱ Six-year periods of data exclusivity are in operation in 7 of the EU Member States i.e. Austria, Denmark, Finland, Ireland, Spain, Greece and Portugal. Norway and Iceland, who also operate EU registration procedures also, have six years periods." First wave" Accession countries i.e. Czech Republic, Cyprus, Hungary, Poland and Slovenia are also expected to operate 6-year protection periods when they are full members of the EU. It is important to stress that in Spain, Greece and Portugal, the six-year data exclusivity period, in accordance with options provided in Directive 65/65 EEC, do not allow the data protection to extend beyond the patent period of the product authorised. Poland, Hungary and Slovenia are also expected to adopt this patent linked formula. Ten-year periods of data exclusivity are in operation in seven EU countries: Belgium, France, Italy, Germany, Netherlands, Sweden and UK. Ten-year period of data exclusivity is granted for all approvals under the Centralised Procedure.

^{iv} Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ L 213 of 30 July 1998.

^v The SPC was introduced in 1992 to compensate the holder of a basic patent for the reduction of effective patent life due to other drug legislation. Compensation was made possible for up to five years, resulting in a maximum effective patent life of 15 years. With these 15 years, as explicitly mentioned in the considerations of the Provision, sufficient protection was made possible. Since that time, actual effective patent life is rapidly nearing the 15 years for the majority of all products. This is reflected in the following tables:

Table 1: Time between date of first marketing in Europe and Marketing Authorisation in individual country.

France	12,2 months
Germany	13,5 months
Netherlands	13,9 months
United Kingdom	12,1 months

Table 2: Average time between Marketing Authorisation in the individual country and the SPC expiry date of all products (A) and percentage of products with effective patent life of 12 – 15 years (B).

	<i>All products (A)</i>	<i>12-15 years (B)</i>
France	13,0 years	71%
Germany	12,6 years	69%
Netherlands	12,8 years	73%
United Kingdom	13,0 years	76%

^{vi} See revised wording of Article 54 (5) of the EPC adopted by the Diplomatic Conference in Munich on 29 November 2000: “Paragraphs 2 and 3 shall also not exclude the patentability of any substance or composition referred to in paragraph 4 for any specific use in any method referred to in Article 53(c), provided that such use is not comprised in the state of the art.”

^{vii} Other countries such as Australia, Canada and New Zealand have 5 years only for NCEs. In the United States, data exclusivity provisions consist of the following:

- 5-year data exclusivity period is granted to the NCE.
- 3 years data exclusivity period for any new indications.
- 6-month data exclusivity period for paediatric indications.

^{viii} Commission Communication on the Single Market in Pharmaceuticals, COM (1998) 588 final of 25 November 1998.

^{ix} See page 42 paragraph 4 of the Cameron McKenna/Andersen Consulting report on the *Evaluation of the Operation of Community Procedures for the Authorisation of Medicinal Products* (November 2000).

^{ix} For further information on Article 39.3 TRIPS please refer to EGA’s position paper “TRIPS Article 39.3 Does Not Require Data Exclusivity Provisions (A Critical Issue For Access To Medicines)” of July 2000.

^x If a patent exists elsewhere, it would imply that the patent holder failed to take the opportunity to apply for a patent in the country where the product is seeking authorisation. Data exclusivity should not be used as a substitute for failing to enforce rights under patent law.