



## **EGA Discussion Paper**

### ***Data Exclusivity and The 2001 Review***

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# Discussion Paper of the EGA

## Data Exclusivity and The 2001 Review

*Following up on earlier communications by the EGA on the subject of data exclusivity<sup>1</sup> this Discussion Paper sets out some of the issues that urgently need to be addressed in the proposals for new legislation in the context of the Review 2001.*

### Introduction

Data exclusivity is regulated by Article 4.8(a)(iii) of Directive 65/65/EEC and interpreted in accordance with several Judgments by the European Court of Justice. The article was introduced in 1965 and only once revised in 1987 by Directive 87/21/EEC with the aim to strike a better balance between the prevention of unnecessary tests on humans and animals and the protection of the innovative pharmaceutical industry. For this purpose it introduced the possibility to refer to studies performed earlier by the innovator - which are included in the application dossier of the innovator - instead of repeating/performing own studies.

The requirements for use of this abridged procedure are:

- The expiry of the period of 6 or 10 years data exclusivity;
- The product of the second - generic - applicant is “essentially similar” to the innovator product;
- The innovator product “is marketed” in the country of application.

### Character of data exclusivity:

It should be noted that after expiry of the period of either 6 or 10 years, the information in the innovator dossier does not become public but the authorities are allowed to use it when assessing the application of the generic applicant. Data exclusivity therefore is not a right of intellectual property, but an exception made by law to the rule that the authorities may not disclose information provided to them confidentially, nor use such information for another purpose than the purpose for which those data were originally provided.

### Audit 2000

The report “Evaluation of the operation of Community procedures for the authorisation of medicinal products” by CMS Cameron McKenna and Andersen Consulting clearly showed data exclusivity as an area justifying critical review. The report draws the following

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<sup>1</sup> Please see EGA Position Paper "*Data Exclusivity: A Major Obstacle to Innovation and Competition in the EU Pharmaceutical Sector*" of December 2000. Available on the EGA website: [http://www.egagenerics.com/facts\\_figures/intellectual\\_property/data\\_exclusivity.htm](http://www.egagenerics.com/facts_figures/intellectual_property/data_exclusivity.htm)

conclusions:

- there is general agreement that greater harmonisation of data protection periods is required between Member States and the different approval systems.
- although the balance to be struck requires careful thought, there is a general view that the subject of article 4.8(a)(iii) urgently requires a clearer definition than currently exists.

## **ECJ *Generics* Judgment**

Over the years the application of Article 4.8(a)(iii) has given rise to many problems of interpretation and subsequent case law from the European Court of Justice. The most recent guidance has been provided by the ECJ in the “*Generics*” ruling (C-368/96, 3 December 1998).

In the *Generics* case, the following question was addressed: If the product of a generic applicant is “essentially similar” to the original product of the innovator and once the 10-year period of data exclusivity of the original product (dossier) has expired, is it then possible for a generic applicant to obtain registration for not only the original indications, dosage forms, doses and dosage schedules, but additionally for the indications, dosage forms, doses and dosage schedules as registered subsequently and which are not yet registered for 10 years?

The *Generics* ruling stipulates that if a generic product is essentially similar (according to the definition thereof as provided by the Ruling), to the original innovator product and the original product has been authorised for more than 6 or 10 years, the generic product can be registered for all indications, irrespective of when such indications were authorised. The same applies for all dosage forms, doses and dosage schedules, provided that these changes to the original product do not preclude essential similarity as defined in the Ruling.

This means that after the *Generics* ruling, new indications in principle do not have an own period of data exclusivity and neither do new dosages and dosage forms, unless they influence “essential similarity”.

The *Generics* Judgment has given rise to problems of interpretation as is evidenced by legal procedures that are pending in several EU Member States.

Furthermore, the effect of the Ruling is countered by *second medical use* patent claims that are interfering more and more with the marketing authorisation process and harmonisation efforts (e.g. the establishment of Euro-SmPCs and the Article 11 arbitration initiative of the Heads of Agencies and the EMEA).

The *Generics* ruling clearly shows the need for clearer definitions in the law, to avoid costly procedures necessary to clarify essential elements of the legislation, thus unnecessarily delaying the access to the market.

## Patent protection

The problems surrounding the application of article 4.8(a)(iii) are enhanced by the interference of patent protection with the marketing authorization process, in particular in respect of second medical use claims.

Patents can be granted with respect to many inventions, e.g. active principles, formulation, manufacturing process, and (second) medical use. The latter has become more and more common. However, it needs to be clarified what the effect of such claims is on the SmPC: Can second indications that are protected by a patent claim still be specified on the generic SmPC, and if not, what is the effect on harmonization and public health?

## Conclusions

### Considering that

- the essential aim of Directive 65/65/EEC is the protection of public health without hindering the development of the pharmaceutical industry;
- protection of innovation is necessary, but a balance needs to be struck and patent laws already provide extensive protection and reward for innovation;
- generic products are essential in light of the need to contain costs and decrease national health budgets;
- the system of patent protection and marketing authorization interfere with one another in the area of second medical use;
- The duration of the data exclusivity period and the definition of essential similarity are intertwined, as the definition of essential similarity actually determines **whether** a generic applicant has access to the abridged procedure. In other words: the definition of essential similarity determines whether reference to a certain originator product and/or its line extensions can be made. If the definition is narrowed, access to the generic procedure is limited. The duration of the period of data exclusivity simply determines as of **when** such reference can be made.

### EGA is of the opinion that:

- Article 4.8(a)(iii) is a very limited legal basis for an important procedure as the generic application procedure. It clearly needs revision to resolve the problems encountered by all that work with it;
- It is in everybody's interest to have the legislator provide a clear understanding of the rules, because, if the legislator does not take its responsibility in this respect, the courts and the ECJ, will take their responsibility without control by the legislator.
- Any decisions on data exclusivity should take into account:
  - the need for a harmonised data exclusivity period;

- the concept of essential similarity, which establishes what are the requirements to be able to extrapolate data from one product dossier to another. (NB: It should be noted that this issue is of primary importance, irrespective of the harmonised period of exclusivity that is chosen);
  - the rapidly expanding use of patent protection of second medical use claims.
- Furthermore it should be taken into account that a further increase in the level of intellectual property (IP) is no longer the answer to promoting pharmaceutical innovation in the European Union. With pharmaceutical companies having a multitude of patents protecting any one product, the EU's pharmaceutical policy has focused too much on IP protection and too little on competition and the necessary business environment for innovation.

**Evaluating the new proposals, the EGA is concerned that**

- The proposed 10+1 year data exclusivity period will result in the originators' effective market protection lasting beyond the period of the basic patent. This is because, during the period of data exclusivity, unlike during the patent period, an application for a generic registration is actually prohibited. Even where data exclusivity periods may lapse before the patent or SPC expiry, the period between the two dates could be far too short to give generic applications enough time to receive authorisation in time for patent/SPC expiry. For this reason we strongly urge the adoption of the shorter basic period of 6 years, and in very exceptional circumstances a very short, once only, incremental period to cover the development of any new use.
- No account is taken of whether the additional indications already have a patent. We believe that an indication with an important clinical benefit in comparison with existing therapeutic products can be patented. Therefore there is no reason to extend the protection of the first authorisation. In fact, the system now proposed could result in delaying the marketing of generics of the original indication(s) of the product. Consequently, we would ask that no additional protection/reward (e.g. in the form of a short incremental period) be given to patented indications.
- Allowing application for an additional 1-year data exclusivity at any time during the 10-year period - rather than within a specific cut-off period - will encourage originators to apply later, rather than earlier. This would a) reduce the period of time that the new indication would be made available to the public and b) create uncertainty for generic companies in making their applications.

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