



Making Medicines Affordable

POSITION PAPER

ACCESS TO GENERIC MEDICINES AND 'TRIPS PLUS' PROVISIONS

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1. Introduction

The European Generic Medicines Association is the official representative body of the European generic pharmaceutical industry, which is at the forefront of providing high-quality affordable medicines to millions of Europeans, and stimulating competitiveness and innovation in the pharmaceutical sector. Formed in 1993, the EGA represents companies employing over 100,000 people in Europe, and plays an important consultative role in European healthcare policy-making. Cost-effective generic medicines save EU patients and healthcare systems over €18 billion each year, thus helping to ensure patient access to essential medicines and providing urgently needed budget headroom for the purchase of new and innovative treatments.

Developments in pharmaceutical law, patent law and international health policy exert a major impact on the generic medicines industry. The EGA especially welcomes the creation in the context of the World Health Organization (WHO) of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) as we believe it provides an important opportunity to address effectively the growing burden of diseases affecting the populations of developing countries, and particularly women and children. The EGA would like to welcome point 6.3(a) of the Global strategy and Plan of Action (GSPA) which recommends to *'support the production and introduction of generic versions of essential medicines in developing countries, including national legislation to encourage generic entry on patent expiry'*.

2. Why is EGA against 'Trips Plus provisions':

In order to ensure access to generic medicines governments from developing and least developed countries should:

- Promote generic medicines
- Use TRIPs flexibilities
- Avoid 'TRIPs Plus' provisions

'TRIPs Plus' provisions offer exclusive rights to originators that go beyond what is mandated by the TRIPs agreement. The consequences are that the local production and marketing of generic medicines are delayed and hindered, prices increase and access to medicines is reduced.

The EGA is very concerned by the growing trend to add 'TRIPs Plus' provisions, which go far beyond the ratified TRIPs agreement, into negotiations on Economic Partnership Agreements (EPAs) and Federal Trade Agreements (FTAs). This practice is having a major negative impact on access to medicines. According to the WHO¹: *'Governments should not 'trade away' people's right to have access to medicines'*

¹ Brief Note of WHO, March 2006



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The EGA recommends providing policy assistance to countries in taking advantage of the existing flexibilities in patent law to increase access to medicines for their populations. In this context, it is crucial that countries negotiating bilateral trade agreements are not forced into implementing TRIPS Plus Provisions such as:

- Data Exclusivity
- Patent Linkage
- Undermining of Bolar provision
- Restrictions to Compulsory Licensing
- Increase in Intellectual Property protection to fight counterfeiting
- Intellectual Property enforcement without safeguards

Data Exclusivity:

Data Exclusivity prevents the regulators from accepting an application for a marketing authorisation during a defined period. After, the regulator can rely on the originator clinical trial data to authorise the generic. Data exclusivity per se is not a requirement of TRIPS. Developing & least developed countries should not be forced to impose stringent data exclusivity requirements which could impede timely access to medicines. Thus, the introduction of new obstacles related to pharmaceutical test data should be avoided.

EGA supports recommendation 4.20 of the WHO CIPIH report that recommends quite clearly that:

“A public health justification should be required for data protection rules going beyond what is required by the TRIPS Agreement. There is unlikely to be such a justification in markets with a limited ability to pay and little innovative capacity. Thus developing countries should not impose restrictions for the use of or reliance on such data in ways that would exclude fair competition or impede the use of flexibilities built in to TRIPS.” (Recommendation 4.20 page 181).

It is also necessary to draw attention to the fact that ‘exclusivity’ and ‘protection from acts of unfair competition’ are not the same and should not be confused. Article 39.3 of the TRIPs Agreement obliges WTO Member States to protect clinical data made for registration purposes against ‘acts of unfair competition’. Data exclusivity prevents the regulatory authorities from making reference to the original clinical data for a defined period, during which no authorisation of generic medicines may take place. Data exclusivity, therefore, provides a form of market exclusivity. However, what Article 39.3 requires is a form of data protection so as to prevent unfair commercial use of the data by third parties. The intention of Article 39.3 is not to create a form of market protection. For this reason it would be unlawful to claim that Article 39.3 requires the introduction of ‘data exclusivity’ provisions as operated in the EU or the USA.



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Patent Linkage:

Patent linkage creates a link between the patent status of a product and the application for a marketing authorisation which prevents the registration and authorisation of generic medicines until after the expiry of patents, and consequently considerably delays generic market entry. This forced 'link' creates an impossible situation, as regulatory authorities lack resources and expertise to assess the validity of each patent, and in any case it is not their duty to do so.

Patent linkage:

- Prevents registration and authorization of the generic until after patent expiry
- Delays generic market entry
- Hinders local production

Furthermore, setting up and maintaining national patent databases is an extremely resource intensive exercise which requires the expertise of IP specialists. One product is usually protected by many different patents and the status of patents is changing (additional patents granted, invalidation of patents etc.) We recognize however the need for relevant government departments to know if there is a patent in place. We believe that the most efficient way to get the patent status of a given medicine is simply to approach the Marketing Authorization Holder directly in the respective country.

Undermining of the Bolar Provision:

The 'Bolar' provision allows all development, testing and experimental work required for the registration of a generic medicine to take place during the patent period of the original product. The purpose of such a provision is to ensure that generic medicines are on the market immediately after patent expiry so as to improve access and to encourage competition. Bolar has become a common feature of patent law both outside and within the EU.

It is highly important that no obstacles are introduced in countries implementing the Bolar provision, otherwise generic medicines could be delayed by approximately two years (ie, the time it takes to obtain marketing authorisation). The Bolar provision should not be open to legal uncertainties and should not fail to cover all activities – such as the provision of samples and the right to export.

Intellectual Property Enforcement:

Intellectual property enforcement provisions should not be expanded without public health safeguards.

In this context, easily granted interlocutory injunctions should not be used to block affordable generic medicines. The EGA is seriously concerned that the civil measures to enforce intellectual property rights can be misapplied and misused by IP holders against legitimate competition in the areas of patents. For this reason, it is important to ensure that the European Commission does not impose the Intellectual Property Rights



Enforcement Directive (Directive 2004/48/EC) on developing countries while omitting the limitations and flexibilities which are available to the EU Member States that have implemented the Directive. It should be noted that Directive 2004/48/EC recognises potential abuses and, in article 3.3, states that ***“the measures, procedures and remedies shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.”***

Restrictions to Compulsory Licenses:

The introduction of restrictions that limit the abilities of countries to make use of compulsory licenses as legal tools to ensure access to low-cost medicines should also be avoided. This goes against the Doha declaration on TRIPs and Public health which gives countries freedom to determine reasons to grant compulsory licenses. Data exclusivity rules should be derogated when a compulsory license is issued in order to facilitate market entry.

In addition to not limiting the legitimate use of compulsory licenses, the EGA considers it necessary to properly assess the incentives – or lack of incentives – given to generic medicines producers to provide medicines for less developed and developing countries.

All of these ‘TRIPs Plus’ provisions essentially damage the balance that was carefully negotiated under TRIPs and clearly limit access to health in economically vulnerable countries. From our standpoint as European generic medicines manufacturers, such TRIPs Plus policies, if introduced in Russia and CIS countries, Middle East and Asian markets, would damage our own efforts to build markets in these developing economies.

3. Counterfeiting issue:

EGA would like to draw attention to the definition of counterfeit drugs developed by the WHO, to wit:

“a medicine, which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.”

In the context of this definition, it is important to note that medicines which are not patented can also be counterfeited and that **counterfeiting is essentially a trademark issue and not a patent issue**. Consequently, counterfeiting is not a reason to increase patent protection or enforce patent rights. If generic medicines are confused with counterfeited drugs because of alleged patent infringement, this will hinder local production and access.



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It is important to not that counterfeiting cannot be used in FTAs/EPAs as a reason to justify:

- Patent extensions or increases of data exclusivity
- The use of harsher civil sanctions and criminal sanctions to punish patent infringements

As a matter of fact, patent infringements are not crystal clear: it can take up to three years to solve a patent infringement case and the decisions can be different in each country. Therefore, enforcement measures to deal with alleged counterfeiting/piracy are not necessarily appropriate for ordinary IP infringement disputes

Counterfeiting must be tackled by taking measures in the areas of criminal enforcement (penal sanctions) and drug regulation (reinforced control by regulatory agencies, improved regulation related to good manufacturing and distributing practices), and not by increasing the levels of intellectual property protection which would be wholly ineffective as well as unjustified.