



Making Medicines Affordable

INTERGOVERNMENTAL WORKING GROUP ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY

EGA Submission to Section 1 Draft Global Strategy and Plan of Action

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.

A) The EGA's Contribution to the IGWG

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 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'*.

In this context, and considering that the generic medicines industry plays an important role in the access to medicines debate, the EGA is keen to contribute the insights into these issues that it has gained through its experience and expertise.

B) Issues to be Prioritised within the Proposed Global Strategy and Plan of Action:

The EGA would like to recommend the following issues to be prioritised within the IGWG Draft Global Strategy and Plan of Action (GSPA). These issues relate mainly to the application of flexibilities, consistent with TRIPs, to the impact of bilateral trade agreements and to the use of compulsory licenses. Our submission focuses principally on two chapters of the GSPA: chapter 5 dealing with 'Intellectual Property Management', and chapter 6 on the 'Improvement of Delivery and Access'.

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 EPAs and FTAs. This practice is having a major negative impact on access to medicines.



There is clearly a need to define these TRIPs Plus provisions. In this context, the EGA strongly supports point 5.2 (a), (b) and (c) of the GSPA. **Nevertheless, we are convinced that the commitment expressed in the GSPA to stop TRIPs Plus provisions is not firm enough.** The EGA recommends therefore that the IGWG provide policy assistance to countries in taking advantage of the existing flexibilities in patent law to increase access to medicines for their populations.

Indeed, it is crucial that countries negotiating bilateral trade agreements are not forced into implementing TRIPs Plus Provisions such as:

1. Patent Linkage:

Creating 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.

In this context, and because it may lead to patent linkage, the EGA is against point 5.1(b) of the GSPA which says:

“compile and maintain national databases on patent status of relevant health related products and promote exchange of information between relevant government departments.”

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.

2. Data Exclusivity:

The introduction of new obstacles related to pharmaceutical test data which delays the registration of generic medicines.

Data exclusivity is mentioned in point (5.3 (c) of the GSPA: ‘Assess the impact of data exclusivity regulations’. **However, the EGA is of the opinion that the GSPA is too neutral on the issue of data exclusivity. It should be more explicit – along the lines of the CIPIH report – on the dangers that extensive data exclusivity regulations represent for access to medicines.** The CIPIH report has already made that assessment and 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.

3. **IP Enforcement:**

Expanding intellectual property enforcement provisions 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.”*

4. **Bolar Provision:**

Clauses aimed at undermining the full implementation and use of the legal measure known widely as 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. A reference to Bolar should be included in the GSPA.



5. Compulsory Licenses:

Restrictions introduction to limit the abilities of countries to make use of compulsory licenses (*mentioned in point 6.3 (d)¹ of the GSPA*) as legal tools to ensure access to low-cost medicines.

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.

C) Any Other Issues to be Considered within the Proposed Global Strategy and Plan of Action:

1. Counterfeiting issue: (*mentioned in point 6.2, e*)

The EGA is very much in favour of ‘*minimising the public health consequences of counterfeit and substandard products*’² in the context of the definition of counterfeit drugs developed by the WHO, to wit:

“a medicine, which is deliberately and fraudulently mislabelled 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 by the WHO, it is important to note that medicines which are not patented can also be counterfeited; counterfeiting is essentially a trade mark issue and not a patent issue. Consequently, counterfeiting is not a reason to increase intellectual property protection. 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.

¹ ‘take necessary legislative steps in countries with manufacturing and export capacity to allow compulsory licensing for export consistent with the TRIPs agreement and the Doha declaration on TRIPs and Public Health’, page 11 of A/PHI/IGWG/2/2, 31 July 2007.

² Point 6.2 (e), page 10 of A/PHI/IGWG/2/2, 31 July 2007.



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2. Quality, Safety and Efficacy of Medicines

EGA would like to suggest expanding on point 6.2(a):

*(a) 'strengthen capacity to monitor the quality, safety and efficacy of health products, and accelerate the regulatory approval of products with potential utility. **One way of accelerating the regulatory approval process of medicines is to take advantage of the scientific opinion drawn up by other jurisdictions or agencies**'.*