EUROPEAN GENERIC MEDICINES ASSOCIATION

Making Medicines Affordable

EGA comments to A/PHI/IGWG/2/Conf.Paper No.1 Rev.1

INTERGOVERNMENTAL WORKING GROUP ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY

Draft Global Strategy and Plan of Action - March 2008

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.

A) The EGA's Contribution to the mission of the IGWG

The EGA 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 especially welcomes 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 believes it is important that the GSPA tries to maintain the balance that was carefully negotiated under TRIPS in order to encourage innovation and access to medicines.

B) Assessment of the draft Global Strategy and Plan of Action

The EGA's comments will focus principally on two chapters of the GSPA: chapter 5 dealing with 'Intellectual Property Management', and chapter 6 on the 'Improvement of Delivery and Access'. Within these chapters, the EGA would like to recommend the following issues to be prioritised:

- The promotion of measures which ensure immediate patient access to generic medicines after patent expiry (such as support for Bolar Provisions, limited data exclusivity, and no patent linkage).
- The application of flexibilities consistent with TRIPs so as to ensure the balance is maintained in TRIPS.

EUROPEAN GENERIC MEDICINES ASSOCIATION
Rue d'Arlon 50 | 1000 Brussels | Belgium
T: +32 (0)2 736 84 11 F: +32 (0)2 736 74 38
www.egagenerics.com info@egagenerics.com

- No restrictions to the Doha compulsory licenses agreement reached in August 2005 and better application of the system at country level in order to make the system work effectively for increasing access to medicines for patients.
- No 'TRIPs plus' provisions in trade agreements, particularly data exclusivity provisions which introduce market protection for originator products as a form of "compensation" for products not entitled to product patent protection under the TRIPS transitional arrangements or used as a pretext for combating counterfeit medicines, which is not a patent or data exclusivity related problem.

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. '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 Asia, would damage our own efforts to build markets in these economies. In this context, the EGA strongly supports point 5.2 (a), (b) and (c) of the GSPA. We specially agree with 5.2 (c) and strongly support subparagraph (b) of 5.2 which says:

> *[avoid the incorporation of TRIPS-plus measures in any trade agreements and in national legislation that may have negative impact on access to health products or treatments in developing countries].* **This subparagraph b) should not be deleted.**

Countries negotiating bilateral trade agreements should not be forced into implementing TRIPS Plus Provisions such as:

1. **Patent Linkage:**

Patent linkage is the practice that 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 the patent, and consequently considerably delays generic market entry.

In this context, and because it may lead to patent linkage, the EGA **asks for the deletion** of the first 3 sentences of **point 5.1(c)** which says:

(c) ~~[to compile, maintain and update user friendly global databases on the status of healthrelated patents in all countries and facilitate widespread access to these databases, in particular by developing countries, [as well as]~~/[to] strengthen national capacities of analysis and the quality of patents.]

Patent linkage creates an impossible situation for regulatory authorities who lack the mission, resources and legal expertise to assess the validity of patents. If we take into account that any single product is usually protected by many different patents and that the status of these patents is subject to change (additional patents granted, invalidation of patents etc.), setting up and maintaining national patent databases is an extremely resource intensive exercise which requires the expertise of IP specialists.

However, we do believe it is important to assess and strengthen the quality of patents. The patent system must not be used to restrict competition from generic medicines by

approving weak patent applications. Whilst patents are indeed clearly important for encouraging innovation, a patent system that is too permissive in granting patent rights will prevent generic competition, restrict access to medicines through decreased affordability, and will ultimately discourage real innovation in the pharmaceutical sector. When patents are aimed solely at excluding competitors from markets, patent quality becomes crucial to ensuring the rights of patients. Therefore we recommend that **point 5.1 c** should remain as follows:

5.1 (c) to strengthen national capacities of analysis and the quality of patents.]

2. Data Exclusivity:

The EGA is against 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 on the dangers that extensive data exclusivity regulations represent for access to medicines. Therefore we propose the following alternative wording for 5.3 c):

> 5.3 c): ***'Reliance on test data by regulatory authorities with the aim to authorize a generic product should not be restricted in ways that would exclude fair competition or impede the use of flexibilities built in to TRIPS.'***

In addition, EGA believes that **subparagraph (c) of 5.3 should be deleted** as follows:

~~*[assess the impact of data-exclusivity regulations on access to drugs in developing countries, taking into account the incentive of such a protection for pharmaceutical companies to register new products on the relevant market.]*~~.

Instead, we support points (5.3) d, e, f, g.

In spite of the fact that, as already mentioned above, point 5.3 (c) is not stringent enough against data exclusivity and should be redrafted as we have suggested, we welcome the fact that it differentiates data exclusivity from data protection; in fact, 'exclusivity' and 'protection from acts of unfair competition' are not the same and should not be confused: 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[1].

3. Bolar Provision:

EGA is against any clause 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

[1] See EGA's first submission to IGWG on the GSPA, Sept. 2007

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 subject to legal uncertainties and should not fail to cover all activities—such as the provision of samples and the right to export.

For these reasons, we welcome the reference to Bolar included in **6.3 g)** page 22:

> *g) reinforce and encourage the use of the Bolar Exception to stimulate entry into market of generics as soon as the patent expires.*

4. Compulsory Licenses:

The EGA is against the introduction of restrictions aimed to limit the abilities of countries to make use of compulsory licenses (*mentioned in point 6.3 (d)*[2] *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. For this reason the EGA supports **point 5.3 a)** which is in favour of alternative incentive schemes for R&D that could facilitate access to medicines.

> *(a) [explore]/[examine] and implement [complementary] / [alternative [and/or additional]] incentive schemes for research and development that separate the incentives for innovation from the prices of health-care products [for example, the prize fund model] / [including, but not limited to, the prize fund model] [, and that are consistent with domestic regimes for protecting intellectual property and rights]*

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

1. Promotion of competition

The EGA is in favour of all the measures proposed in the GSPA to promote generic medicines such as in 6.3 a), d), e) + the group g) to k).

[2] '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', 6.3 d, page 11.

Making Medicines Affordable

2. **Counterfeiting issue:** (*mentioned in point 6.2, f*)

The EGA is very much in favour of '**6.2 (f)** *[develop legislation and strategy against] / [minimize] the public health consequences of counterfeit and [substandard] / [spurious] products*[3]', 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 trademark issue and not a patent issue. Consequently, counterfeiting is not a reason to increase intellectual property protection and we wish to raise serious concerns about attempts to confuse the anti-counterfeiting issue with patent enforcement. Unjustifiably treating generic medicines on a par with potentially dangerous counterfeit drugs in cases of alleged patent infringement will only hinder patient access to these affordable medicines and will not increase public safety. In this context we would like to add the following sentence to the wording of **6.2 f**:

> **6.2 (f)** *[develop legislation and strategy against] / [minimize] the public health consequences of counterfeit and [substandard] / [spurious] products.* ***Counterfeiting must be tackled by criminal enforcement measures (i.e. penal sanctions) and drug regulation (reinforced control by regulatory agencies, improved regulation related to good manufacturing and distributing practices), and not by increasing patent protection or by introducing harsher civil measures to enforce patents.***

3. **Quality, Safety and Efficacy of Medicines**

The EGA would like to suggest expanding on point **6.2(a)** with the following sentence at the end:

(a) [develop and] strengthen [[medicines] / [drugs] regulatory authority] capacity to monitor the quality, safety and efficacy of [priority] health products [and services], and [accelerate] / [prioritize] the regulatory approval of [strategic] [life-saving] products [with potential utility] [for national public health programs][while maintaining quality and respecting ethical review standards]. '***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'.***

[3] Point 6.2 (f), page 21