Making Medicines Affordable

Brussels, 25 April 2006

Mr President
Ivan Gasparovic, doc., JUDr, PhD.
Stefanikova 2, P.O.Box 128,
810 00 Bratislava 1
The Slovak Republic

RE: **Revision of the Act 140/ 1998** relating to medicinal products and medical devises is Contrary to EU Pharmaceutical Legislation

Dear Mr. President,

The European Generic medicines Association (EGA[1]), of which several of the local Slovak medicines manufacturers are members, has taken a direct interest in the revision of the Act 140/ 1998 relating to medicinal products and medical devises.

Accordingly to the new §21a par. 8 g) of Act 140/ 1998 as revised, the State Institute can reject the application for registration of generic medicine, if reference product or active substance used in the reference product is protected by patent or by supplementary protection certificate (SPC).

This provision **is contrary to the Directive 2001/83/EC as modified by Directive 2004/27/EC**.

Consequently, we would ask you to prevent an abuse of the EU law from happening in the Slovak Republic **by not signing the revision of the Act 140/ 1998.** If this provision is not withdrawn, we have already discussed with the European Commission of the formal infringement action against the Slovak Republic. Any attempt to create patent linkage is a clear abuse of the EU regulatory system, and is purposefully confused with US practices which have no application to the EU regulatory system. There is no legal basis in Europe for linking the patent status to the approval, pricing or reimbursement process of medicinal products.
Should you need any further information on this issue or wish to discuss this with us in more detail, please do not hesitate to contact us.

Yours Sincerely,

Greg Perry
Director General

[1] *The EGA 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.*

EUROPEAN GENERIC MEDICINES ASSOCIATION
Rue d'Arlon 15 B-1050 Brussels Belgium
T: +32 (0) 2 736 84 11 F: +32 (0) 2 736 74 38
E: info@egagenerics.com www.egagenerics.com
VAT: BE 449 332 209

Making Medicines Affordable

EGA Statement on Revision of the Slovak Republic Act 140/ 1998 relating to medicinal products and medical devises

In accordance with the new §21a par. 8 g) of Act 140/ 1998 as revised, the State Institute can reject the application for registration of generic medicine, if reference product or active substance used in the reference product is protected by patent or by supplementary protection certificate (SPC).

In addition, the Ministry of Health of the Slovak Republic already issued the Guideline of No. LP/31/2006-SF on January 10, 2006, laying down the procedure for evaluation of applications for registration of medicinal products for human use by the State Institute for Drug Control from the patents protection as well as the supplementary protection certificates point of view.

We have carefully analyzed the articles contained in new §21a par. 8 g) of Act 140/ 1998 as revised and the Guideline No. LP/31/2006-SF, concluding that they will create an alarming situation whereby *'The State Institute shall refuse the application for marketing authorisation of a medicinal product, if the medicinal product concerned or the active pharmaceutical ingredient incorporated in the medicinal product concerned is subject to a protection by the relevant patent document or by the supplementary protection certificate, provided that the subject of the application for marketing authorisation is not the original medicinal product (§ 21, Art. 12 of the Act). Notwithstanding the foregoing, the application may be refused, as provided by § 21a, Art. 5 of the Act.'*

We are very keen to ensure that this new legislation in Slovakia is developed within the legal framework established in the relevant Directives, Regulations and practices of the European Union in order to avoid any eventual judicial conflict.

This request of linking the evaluation of generic medicines' application with patent protection as proposed in a new §21a par. 8 g) of Act 140/ 1998 as revised and Guideline LP/31/2006-SF is contrary to European law and current regulatory practice in the EU practice.

- An EU Regulatory Authority has neither a mandate nor the competency to assess the patent status of products. Their role is rightly and strictly limited to assessing the safety, efficacy and quality of medicinal products.

- Preventing an authority from accepting an application for a generic medicine during the patent period is also contrary to both the letter and the spirit of the EU Bolar provisions.

- Refusing the application for registration of a medicinal product, if the medicinal product or the active substance of the medicinal product is protected by patent or protected by supplementary certificate, when the subject of the application for registration of medicinal product is not a reference product (original product) is

EUROPEAN GENERIC MEDICINES ASSOCIATION
Rue d'Arlon 15 B-1050 Brussels Belgium
T: +32 (0) 2 736 84 11 F: +32 (0) 2 736 74 38
E: info@egagenerics.com www.egagenerics.com
VAT: BE 449 332 209

Making Medicines Affordable

contrary to the new EU pharmaceutical legislation, in particular to Article 10.6. of Directive 2001/83/EC as amended.

- Furthermore, in the minutes of the Council Working Party on Pharmaceuticals of 23rd April 2003, a footnote mentions that '*the submission and subsequent evaluation of an application for a marketing authorisation as well as the granting of an authorisation are to be considered as administrative acts and consequently falling outside the scope of patent protection.*'

- Finally, linking registration of generic medicinal products to the patent status of the reference product is contrary to the EU registration procedures (Decentralised and Centralised Procedures). If this provision and the guideline remain in force, the Slovak Republic can never act as Reference Member State in the Decentralised Procedure, and generic companies have to exclude Slovak Republic as concerned Member State in all first round decentralised procedures.

Any attempt to create patent linkage is a clear abuse of the EU regulatory system, and is purposefully confused with US practices which have no application to the EU system. Furthermore, in the WTO's Agreement on Trade-Related Intellectual Property Rights ('TRIPS Agreement'), there is no reference to any obligation to link patents to registration or reimbursement of medicinal products, and on the contrary, the preamble recognises that IP rights are 'private rights', i.e. it is up to patent holders to enforce their rights, not Regulatory Authorities.

Under the revision of the Act 140/ 1998 and the Guideline LP/31/2006-SF, a generic submission and therefore the granting of the marketing authorization would be delayed by several years, pushing back the availability to patients of lower-priced equivalent generic products.

Consequently, we would ask you to prevent an abuse of the EU law from happening in the Slovak Republic by not signing the revision of the Act 140/ 1998 and consequently by withdrawing Guideline LP/31/2006-SF. If this provision is not withdrawn, we have already discussed with the European Commission of the formal infringement action against the Slovak Republic. Any attempt to create patent linkage is a clear abuse of the EU regulatory system, and is purposefully confused with US practices which have no application to the EU regulatory system. There is no legal basis in Europe for linking the patent status to the approval, pricing or reimbursement process of medicinal products.

EUROPEAN GENERIC MEDICINES ASSOCIATION
Rue d'Arlon 15 B-1050 Brussels Belgium
T: +32 (0) 2 736 84 11 F: +32 (0) 2 736 74 38
E: info@egagenerics.com www.egagenerics.com
VAT: BE 449 332 209