EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Consumer goods
Pharmaceuticals

Brussels, **20 FEV. 2006**
ENTR/F/2/CSK/IS/D/35236(2005)

Subject: Tamiflu application and data exclusivity in an emergency compulsory licence situation

Dear Mr. Perry,

You asked us to look at the question of data exclusivity under the European pharmaceutical legislation in case a compulsory (patent) licence would have been granted for the marketing of Tamiflu within the European Union.

1. *Compulsory licensing for marketing within the EU is a matter of national law*

First, we would like to clarify that it is a matter of Member State's patent laws to decide under which conditions (compulsory or voluntary) patent licences are granted for production and sale of the patented product within their territory. For instance, Member States' laws may allow for compulsory patent licences to be granted in cases of a national emergency.

2. *Regulatory requirement for EU marketing authorisation; data exclusivity and marketing protection*

Under the European pharmaceutical legislation, applicants for an authorisation to market a medicinal product in the EU have to provide, among other things, the results of pre-clinical tests and of clinical trials to the competent authority. There is an *exception* to this rule if data and marketing exclusivity have expired: the applicant has to demonstrate that the medicinal product in question is a *generic of a reference medicinal product authorised in the EU for not less than 8 years*[1]; if these conditions are fulfilled, the generic product can be placed on the market 10

[1] See, for products authorised under the centralised procedure: Article 6 and Article 14(11) of Regulation (EC) No 726/2004 read in conjunction with Articles 8(3)(i) and 10(1) of Directive 2001/83/EC.

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years after the initial marketing authorisation for the reference medicinal product has been granted.[2]

No exception from data and marketing exclusivity

The European pharmaceutical legislation does not foresee any exception to the above-mentioned periods of 8 year data exclusivity and 10 years marketing protection in case of emergency situations or in case a compulsory patent licence has been granted by an EU Member State.

This means that an applicant for a marketing authorisation in the EU would have to provide the required documentation on pre-clinical tests and clinical trials as required under Article 8(3)(i) of Directive 2001/83/EC, or submit an informed application under Article 10c of Directive 2001/83/EC.

3. *The draft Compulsory Licensing Regulation*

You mention that a provision on the derogation from data exclusivity periods exists under the draft Compulsory Licence Regulation, which is currently in the legislative co-decision process. Indeed, Article 16(2) of the draft Regulation provides that the data protection periods set out in Regulation (EC) No. 726/2004 and in Directive 2001/83/EC are not applicable.[3] However, this provision under the Compulsory Licensing Regulation – if adopted by the European Parliament and the Council – exclusively applies to compulsory licences granted under specific circumstances for medicinal products to be exported outside the EU. The draft Regulation is *not applicable* in case a European Member State issues a *compulsory licence for marketing within the EU.*

4. *Conclusion*

National emergency provisions in an EU Member State may allow the granting of a compulsory patent licence which would allow a generic or other company to use the patented product in the Member State in question.

However, the Community pharmaceutical acquis does not currently contain any provision allowing the waiver of the rules on data exclusivity and marketing protection periods described above in the case of a national or an EU-wide emergency.

Before the expiry of the data exclusivity and marketing protection periods provided for by the European pharmaceutical legislation, applicants for a generic marketing authorisation have to either *(1) provide* the relevant authority with the

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2 Article 14(11) of Regulation (EC) No 726/2004; Article 10(1) of Directive 2001/83/EC.

3 Article 16(2) of the current draft of a Regulation of the European Parliament and of the Council on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems reads as follows: "*If the request for any of the above procedures concerns a product which is a generic of a reference medicinal product which is or has been authorised under Article 6 of Directive 2001/83/EC, the protection periods set out in Article 14(11) of Regulation (EC) No 726/2004 and in Articles 10(1) and 10(5) of Directive 2001/83/EC will not apply.*"

required documentation on *pre-clinical tests and clinical trials* or *(2)* confirm that *the marketing authorisation holder has consented* to the use of the required documentation by the applicant.

Yours sincerely,

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