



Making Medicines Affordable

POSITION PAPER

PATIENTS MUST HAVE IMMEDIATE ACCESS TO AFFORDABLE GENERIC MEDICINES AT DAY ONE AFTER PATENT EXPIRY

**EGA RESPONSE TO THE PUBLIC CONSULTATION
DG Competition Pharmaceutical Sector Inquiry: Preliminary Report**

**EXECUTIVE SUMMARY
31 January 2009**



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1. EXECUTIVE SUMMARY

1.1. Introduction: The Findings of the Preliminary Report Confirm the Experiences of the Generic Medicines Industry

In her speech launching DG Competition's preliminary report on the pharmaceutical sector inquiry (the 'Report') on 28 November 2008, Commissioner Neelie Kroes clearly identified the Report's unspoken conclusion:

“competition in this industry does not work as well as it should”.¹

Among others, the Report rightly identifies delays to generic entry as an important failure of the competitive process in the pharmaceutical sector. The result is that national healthcare systems (and patients) pay unnecessarily high prices for pharmaceuticals and, ultimately, that patients are unable to obtain the medicines they need.

The behaviour of originator companies is correctly stated to be a significant factor in delays to the entry of generic medicines. As set out in the Report, originator companies have a “tool-box” of strategies which they deploy to frustrate the entry of generic medicines. In the opinion of the EGA, the following strategies are the most significant in creating hurdles to generic competition:

- interference in the grant (and/or activation) of marketing authorizations and pricing and reimbursement status;
- seeking weak or invalid patents, particularly second-generation patents – which may form part of a ‘patent thicket’ or be used to block the entry of generic medicines in other ways;
- evergreening – e.g., switching patient demands by launching second-generation products with little or no added therapeutic value;
- information and marketing campaigns that question the quality, safety and efficacy of generic alternatives;
- vexatious litigation whose primary purpose is to delay the entry of generic medicines (e.g., by obtaining interim injunctions keeping generic companies off the market).

¹ Neelie Kroes, “Antitrust: Report of sector inquiry into pharmaceuticals”, Speech 08/659, Brussels, 28 November 2008, available at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/speech_nk_hearing.pdf?reference=SPEECH/08/659&format=HTML&aged=0&language=EN&guiLanguage=en



In highlighting these strategies, the Report confirms the experiences of generic companies operating in Europe. The EGA's members regularly encounter use of each of these strategies when seeking to launch new generic products in EU markets, and will frequently encounter the use of multiple strategies by an originator company in relation to a single medicine and across a range of Member States.

1.2. EGA Recommendations

Where originator companies' use of strategies within the 'tool box' give rise to an infringement of EU competition rules, enforcement action by the European Commission will be appropriate. However, the EGA believes that such action will not, alone, resolve the serious issues identified in the Report. Regulatory changes will be required in addition and will, in many cases, be more effective.

There are a number of reasons for this. First, the barriers to generic entry identified in the Report are not purely the result of originator behaviour: weaknesses in the existing EU regulatory structures play a crucial role. Second, the pursuit of enforcement action under competition rules is a burdensome process: it will not be possible to address all potential infringements via this route. Third, originator behaviour that delays generic entry has a significant negative impact on the cost of healthcare and patient welfare even where the originator responsible is not considered dominant and, as a result, no infringement of competition rules can occur.

The EGA therefore calls on DG Competition to seek the following changes to the regulatory framework in the EU, which the EGA regards as both urgent and critical:

• In Relation to Interference in Regulatory Procedures of Generic Medicines

Processes for the grant of marketing authorizations and pricing and reimbursement status currently represent a severe bottleneck to generic entry, a situation made worse by originator interference in these processes. Existing EU (and Member State) legislation in relation to both marketing authorization and pricing and reimbursement processes should be clarified to make it unambiguously clear that:

- national authorities should not receive or take account of third party submissions when considering the grant of marketing authorizations or pricing and reimbursement status – pharmaceutical legislation should therefore include a provision clearly prohibiting third party interventions;² and
- it is contrary to EU law to take account of the patent status of the originator's reference product in the context of applications for pricing and reimbursement status. This tactic is known as patent linkage and is contrary to the so-called 'Bolar provision' in the pharmaceutical legislation³. The EGA urges the European

² Absent an absolute ban, changes should be introduced (i) to prevent third party interventions delaying the activation of marketing authorizations once granted and (ii) to give generic companies access to complete information as to the existence and content of third party interventions.

³ Article 10(6) of Directive 2001/83/EC (as amended by Directive 2004/27/EC) ("Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential



Commission to modify existing EU legislation to include (a) an express mention of price and reimbursement procedures in the Bolar provision and (b) an equivalent provision (or provisions) in the Transparency directive.⁴

• In Relation to Applications for Weak or Invalid Patents

The majority of the strategies within the originator ‘tool-box’ – including patent thickets, evergreening and vexatious litigation – are only viable because it is currently too easy to obtain weak and ultimately invalid patents through the patent granting process. Therefore, the EGA recommends “raising the bar” in terms of the assessment of patent applications at the EPO and national patent offices by:

- ensuring more rigorous assessment of existing patentability requirements – including in particular application of the inventive step requirement;
- ensuring that applications for divisional patents do not cover essentially the same subject-matter as the parent application;
- increasing the resources available to the EPO in order to allow more rigorous assessment;
- imposing a ‘duty of candour’ on patent applicants requiring them to disclose all information known to them which is material to the patentability of the invention; and
- introduction of measures to reduce the length of opposition procedures and appeals to the Board of Appeals at the EPO, such as the introduction of strict timetables and measures to reduce delaying tactics.

• In Relation to Evergreening Strategies

Where evergreening strategies give rise to an infringement of EU competition rules, the EGA strongly supports enforcement action by the European Commission.

In particular the EGA supports action against originator strategies which are based on the introduction of second-generation products which have little or no added therapeutic value and are often designed to frustrate generic entry by misleading patient or prescribing choice. Examples include strategies in which:

- the original version of the product is withdrawn from the market without objective justification as a means to facilitate the switching of patients to the follow-on product; and/ or
- misleading claims are made as to the added therapeutic value of the follow-on product in order to induce the switching of patient or prescribing intentions

Second generation products with little or no added therapeutic value should be distinguished from incremental innovations which involve changes to existing products

practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products”).

⁴ Council Directive 89/105/EEC relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems (the “Transparency Directive”).



that bring proven added therapeutic value to patients. (e.g. through improved formulations or delivery mechanisms).

- **In Relation to Information and Marketing Campaigns that Call into Question the Efficacy, Quality or Safety of Generic Products**

Information and marketing campaigns by originators that call into question the efficacy, quality or safety of generic products cause significant harm to generic entry and are, by their very nature, misleading given the need to establish the quality and the bio-equivalence of generic products as part of the marketing authorization process. Therefore, the EGA requests the introduction of a specific prohibition on negative information and marketing campaigns (including negative comparative advertising vis-à-vis originator products).⁵

- **In Relation to Vexatious Litigation**

Where litigation – or the threat of litigation – is used by originators purely as a tactic to delay generic entry (rather than a serious attempt to enforce legal rights), the EGA believes that action under EU competition rules may be appropriate. However, bringing individual competition law cases will not address the underlying structural issues in relation to patent litigation in the EU.

In terms of reducing unnecessary and inappropriate delays to the launch of generic medicines, the critical actions are steps to ensure that:

- in all jurisdictions, patent cases are handled by specialized patent judges with the necessary technical knowledge and expertise to decide cases quickly and correctly; and
- the current over-readiness of certain jurisdictions to grant interim injunctions excluding generic products from the market is addressed (the introduction of suitably expert specialist judges would represent a major step forward in this regard).

The Report suggests that the structural issues in relation to patent litigation in the EU may best be addressed through the introduction of a Community patent and a unified judiciary. Whether or not this is the case will depend crucially on the detail of the proposals. Proposals that do not address the urgent need for expert judges and the over-use of interim injunctions will not resolve many of the key problems identified in the Report. The EGA will therefore carefully monitor any detailed proposals once they emerge.

1.3. Comments on Settlement Agreements

The EGA is concerned by the chapter of the Preliminary Report dealing with patent settlement agreements. The chapter appears to suggest that DG Competition may be

⁵ Although such information and marketing may be prohibited under national rules on unfair advertising or competition in some Member States, the position varies across the EU and the general prohibitions are insufficiently precise to constitute an effective deterrent to this form of behavior.



considering following the approach of the US Federal Trade Commission (“FTC”) under US antitrust law in the Schering-Plough litigation and pursuing cases against so-called ‘reverse payment’ settlements (i.e., settlements involving a payment from an originator to a generic). The EGA does not believe that such a course of action would be appropriate. The FTC’s approach in Schering-Plough has been rejected – and subject to serious criticism – by both the US Department of Justice (“DOJ”) and the US Courts.

For the reasons of law and policy articulated by the US Courts in particular, the EGA believes that settlement agreements which do not delay generic entry beyond the term (or scope) of patent exclusivity should not be considered to infringe EU competition law (absent exceptional circumstances).

If, despite this, DG Competition decides to pursue individual cases against reverse payment settlements, it should follow the approach of the FTC in its most recent litigation and do so on the basis of a monopolization theory under Article 82 of the EC Treaty.

1.4. Comments on Bottlenecks in the Regulatory Framework

As mentioned above, the EGA recognizes that the barriers to generic entry identified in the Report are not purely the result of originator behaviour. An important source of delays not caused by originator behaviour is the existing procedures for granting marketing authorizations and price and reimbursement status. The EGA has constructively collaborated in several projects, e.g. The High Level Pharmaceutical Forum, with EU and national authorities on these issues and is committed to continuing such collaboration. The two main issues to be resolved in this area are:

- failure of the concept of mutual recognition between Member States with regard to registration procedures, which has led to a lack of resources and access to quality assessment resulting in difficulties in booking slots for new applications and delays in approvals; and
- the absence of processes for granting automatic price and reimbursement status to generic medicines (which by definition lead to increased competition with the reference product) after the expiry of patent exclusivity.