

EU COMPETITION INQUIRY INTO PHARMACEUTICALS SECTOR

17 January 2008

On 16 January 2008, the European Commission (the Commission) announced a competition inquiry into the pharmaceutical sector. The inquiry is focused on medicines for human consumption, including all prescription medicines.

The Commission is apparently concerned that competition may not be functioning effectively in the pharmaceuticals sector and cases such as *AstraZeneca*¹ have provided anecdotal evidence. The Commission has observed, in particular, that fewer new pharmaceuticals are being brought to market and that the entry of generic pharmaceuticals sometimes seems to be delayed.

Against the background of these concerns, the Commission has already carried out a number of dawn raids on certain pharmaceutical companies. As reported in the *Financial Times* to date, these include generics company, Teva, and branded pharmaceuticals Pfizer, GSK, Sanofi-Aventis, AstraZeneca, Boehringer-Ingelheim and Merck. Those fortunate enough to have escaped a visit from the Commission may well face detailed questionnaires in the future. Indeed, the next 18 months look set to be challenging for the industry, with the prospect of specific enforcement actions, depending on the Commission's findings.

Legal Background

Article 17 of Council Regulation (EC) 1/2003 empowers the Commission to conduct general inquiries into any particular sector of the economy where it is thought that competition may be restricted or distorted. Indications that specific companies have infringed the relevant EC Treaty provisions on competition (Articles 81 and 82 EC Treaty) are not required. The Commission will use a sector inquiry, rather than its other competition enforcement powers, if it has concerns that a market is not working effectively but wants to improve its knowledge to better understand the reasons why.

The adoption of a decision to conduct an inquiry under Article 17 gives the Commission a range of significant investigative powers, including the power to request information, to take statements and impose sanctions for non-compliance with information requests. The Commission also has the power to undertake unannounced inspections ("dawn raids") of business premises within the framework of the inquiry.

Dramatic Inquiry Launch

The Commission launched the inquiry by carrying out a number of unannounced dawn raids on innovative and generic pharmaceutical companies. This represents a departure from Commission practice; previous sectoral inquiries have been launched with questionnaires being sent to companies.

According to the Commission, this particular approach was adopted to ensure that it obtained immediate access to the relevant information. The Commission is most interested in information relating to the use of intellectual property rights, litigation and settlement agreements. This information is by its nature highly confidential and may easily have been withheld, concealed or destroyed following the announcement of the inquiry.

1. COMP/37.507 — Generics/Astra Zeneca, Commission Decision of 15 June 2005.

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This memorandum is intended only as a general discussion of these issues. It is not considered to be legal advice. We would be pleased to provide additional details or advice about specific situations. For additional information on this important topic, please feel free to call upon your Dewey & LeBoeuf relationship partner.

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Anti-competitive Practices?

The inquiry will investigate commercial practices, and in particular, patenting or the exercise of patents, which may not necessarily serve to protect innovation but to block innovative and/or generic competition, litigation (which may be vexatious) and agreements such as settlements in patent disputes which may be collusive.

The inquiry will examine whether such commercial practices may infringe the EC Treaty's prohibition on restrictive business practices (Article 81 EC). It will also consider whether companies may have created artificial barriers to entry, through the misuse of patent rights, vexatious litigation or other means, and whether such practices may infringe the EC Treaty's ban on abuses of dominant market positions (Article 82 EC).

Timing

The Commission's next step will likely be to send information requests to sector participants and it cannot be excluded that further dawn raids may also take place.

The Commission intends to publish an interim report for consultation in 2008, and there will in all probability be a public hearing at that time, when the Commission announces its interim findings. The Commission's final report is expected in spring 2009.

To the extent that the inquiry reveals anti-competitive practices by particular companies, the Commission may open specific competition proceedings against individual entities. This may also lead to class action disputes.

While it is far too early to predict the outcome of the inquiry, it is clear that affected companies must prepare to defend their practices in this sector both within the EU and elsewhere, not least to defend against the class actions that would inevitably follow any adverse findings.

For further information, please contact Dr. Peter Crowther at +44 20 7459 5112 or peter.crowther@dl.com, or contact your Dewey & LeBoeuf relationship partner.

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London
No. 1 Minster Court
Mincing Lane
London EC3R 7YL
Facsimile: +44 20 7459 5099
Peter Crowther
peter.crowther@dl.com
+44 20 7459 5112