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COMMISSION OF THE EUROPEAN COMMUNITIES

Strasbourg, 15.01.2008
C(2008)

COMMISSION DECISION

of 15 January 2008

initiating an inquiry into the pharmaceutical sector

pursuant to Article 17 of Council Regulation (EC) No 1/2003

(Case No COMP/D2/39.514)

(ONLY THE ENGLISH, FRENCH, GERMAN and DUTCH TEXTS ARE AUTHENTIC)

COMMISSION DECISION

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initiating an inquiry into the pharmaceutical sector

pursuant to Article 17 of Council Regulation (EC) No 1/2003

(Case No COMP/D2/39.514)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty¹ and, in particular, Article 17 (1) thereof,

Whereas:

- (1) According to Article 17 (1) of Regulation (EC) No 1/2003 the Commission may decide to conduct an inquiry into a particular sector of the economy or into particular types of agreements across various sectors, "where the trend of trade between Member States, the rigidity of prices or other circumstances suggest that competition may be restricted or distorted within the common market".
- (2) The pharmaceutical industry is knowledge-based. As regards medicines for human consumption, undertakings compete against each other either with patent-protected medicines, or, after patent expiry, with generic medicines.
- (3) Certain circumstances relating to competition by innovative and generic medicines in general suggest that competition may be restricted or distorted in the pharmaceutical sector in Europe, such as a decline in innovation as measured by the number of novel medicines reaching the market and instances of lacking timely entry by suppliers of generic medicines.
- (4) There are indications of commercial practices by pharmaceutical suppliers including notably patenting or the exercise of patents which may not serve to protect innovation but to block innovative and/or generic competition, litigation, which may be vexatious, and agreements, which may be collusive.
- (5) These practices may cause market distortion when they unduly fence off incumbent suppliers of drugs from innovative or generic competition, for example, due to *de facto* extended patent protection through unilateral conduct or agreements. Such practices may

¹ OJ L1, 4.1.2003, p. 1. Regulation as last amended by Regulation (EC) No 1419/2006 (OJ L 269, 28.9.2006, p.1).

limit consumer choice, reduce economic incentives to invest in research and development of new products and damage public and private health budgets.

- (6) In order to establish the extent of the above-mentioned practices and to assess them fully in their proper factual and economic context, the use of formal investigative powers such as those granted to the Commission for sector inquiries is required.
- (7) It is therefore appropriate to initiate a sector inquiry in the pharmaceutical sector within the Community to allow the Commission to use its powers of investigation in particular with respect to pharmaceutical suppliers of innovative and generic medicines for human consumption, consumer and professional organisations in health care, as well as authorities granting patents and marketing authorisations for drugs.
- (8) To the extent that the inquiry into the pharmaceutical sector reveals the possible existence of anticompetitive agreements or practices or abuses of a dominant position, the Commission or, where appropriate, the national competition authorities could envisage taking the appropriate measures to restore competition in the sector, including opening investigations against individual entities possibly resulting in decisions based on Article 81 and/or Article 82 of the Treaty.

HAS DECIDED AS FOLLOWS:

Sole article

An inquiry is hereby initiated in the pharmaceutical sector in the Community, relating to the introduction of innovative and generic medicines for human consumption onto the market.

Done at Strasbourg, 15 January 2008

For the Commission

Neelie KROES

Member of the Commission