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DIRECTORATE FOR FINANCIAL, FISCAL AND ENTERPRISE AFFAIRS
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Working Party No. 2 on Competition and Regulation

COMPETITION IN THE PHARMACEUTICAL INDUSTRY

-- European Commission --

This note is submitted by the Delegation of European Commission to the Working Party No. 2 FOR DISCUSSION at its next meeting on 7 June 2000.

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European Commission

General remark:

The questions in the "Guide for country submissions" are mainly addressed to Member States. In its written submission the European Commission's Directorate General (DG) for Competition will therefore comment only on questions which are directly related to competition issues as set out in Chapter IV of the catalogue.
Only reported cases are commented upon. For reasons of confidentiality DG Competition is not in a position to comment on any pending cases.

4.1 Does the competition law apply to the different components of this sector (manufacturing, health services, distribution and pharmacies) without exemption or exception. Which agency is responsible for enforcing competition law in this sector ?

1. Exceptions/Exemptions : There are no sector-specific exceptions or exemptions of a regulatory nature. The EC Treaty provisions concerning competition contain, however, certain general derogations (state aids: Art. 87 (3) EC-Treaty) or exemptions (agreements: Art. 81 (3) EC-Treaty) which can be applied in the pharmaceutical sector as in any other sector.

2. Responsible Agency : The Commission's Competition DG is responsible for applying competition law in this sector. Within this DG there is a unit in charge of state aids. Mergers are handled by a separate directorate. As to the traditional anti-trust issues raised by concertation or unilateral behaviour of pharmaceutical producers and distributors, these are dealt with by the unit specifically responsible for pharmaceutical products, whereas the health insurance schemes fall within the ambit of the unit responsible for financial services.

4.2 Market Definition

a) Have you had the occasion to address the definition of relevant market in the pharmaceutical sector?

3. The Commission is required to define the relevant product market as well as the relevant geographic market in each case. Even if certain markets have been dealt with in previous Commission decisions, this earlier assessment can only serve as an indicator. The Commission is indeed required to make a fresh analysis of the conditions of competition which might not necessarily be based on the same considerations[1].

b) Did you find that the relevant product market could be approximated by commonly-accepted therapeutic groups ?

4. According to the Commission's Notice on the definition of relevant markets for the purpose of Community competition law[2], demand-substitutability is an important factor for assessing which products compete with each other in the same market. In the pharmaceutical area this obviously refers to the

therapeutic indication for which the medicine will be applied. It would therefore be desirable if the relevant product market could be approximated by commonly-accepted therapeutic groups.

5. This is especially important in light of the fact that without in-depth medical insight it is extremely difficult for DG Competition to inquire about substitutes and to develop the correct market definition. The DG Competition services will typically request in-depth information from the notifying parties or complainants. They will then regularly double-check that information with the market (competitors and customers). In the case of an ex-officio procedure, the Commission is left on its own. A commonly-accepted therapeutic grouping could therefore serve as a means for verifying information given by the parties or for starting an investigation.

6. However, it needs to be clearly understood that any comprehensive listing of therapeutic groupings, although most desirable and useful, can only serve as a first screening tool for market analysis and cannot produce any binding effect whatsoever. Experience shows that therapeutic listings, if they are to serve any meaningful purpose, cannot be too broad and will focus on product groups which are *normally* used for the same therapeutic indication. Nevertheless, pharmaceutical medicines can have various therapeutic indications and many diseases can be treated with a variety of products which do not belong to the same therapeutic grouping. In this case, an independent market analysis will always be necessary. Results might deviate from the commonly-accepted standard.

7. In addition, antitrust and merger decisions increasingly concern innovative markets for which a commonly-accepted standard has not yet been developed. Existing therapeutic classifications can give a first indication, but might no longer serve a suitable basis for finding competing substitutes in this new market. Any commonly-accepted standard should therefore be drafted in such a way that it can be easily amended in order to take due account of new developments. This of course means that the adoption process for new therapeutic categories does not involve too complicated a procedure.

c) What techniques did you use to determine whether certain products were effective substitutes ?

8. The Commission has established a number of principles in its practice,[3] especially in the field of mergers. Product markets in the pharmaceutical industry can be grouped into pharmaceutical specialities, active substances and future products[4.]

9. Pharmaceutical specialities: These are used for the treatment of human illnesses and diseases. The Commission has often used the "Anatomical Therapeutic Chemical" (ATC) classification recognised by the World Health Organisation (WHO). The third level of the ATC classification which groups medicines in terms of their therapeutic indications, is very often used as an operational market definition. However, as already pointed out earlier, ATC 3rd level might not in all cases be an appropriate instrument and it might be necessary in certain cases to carry out analyses at other levels of the ATC classification. For example, it may be necessary to bring certain groups of pharmaceutic specialities together in a broader market. On the other hand, it might also be necessary to apply a narrower market definition where the pharmaceutic specialities forming part of a certain ATC 3 class have clearly differing indications.

10. Very often notifying parties or complainants refer to a different ATC classification, namely the one established by the European Pharmaceutical Market Research Association (EphMRA). This ATC classification is based on the market data of Intercontinental Medical Statistics (IMS). IMS is a market research company which gathers and sells market data for the pharmaceutical sector. Quite often, the IMS system is quicker to take up new developments – e.g. emergence of new drugs – and might therefore provide a clearer picture of recent market developments.

11. The Commission has accepted the use of IMS data and the EphMRA classification in some cases.[5] Given the fact that the WHO and the EPHRMS classifications are similar, but nevertheless have distinct differences (e.g. the number of ATC levels) it would be desirable to reach a common standard.

12. Active substances: The manufacturing process for pharmaceutical drugs includes two separate steps: the manufacturing of active substances, followed by the manufacturing of pharmaceutical products. The Commission considers that active substances are separate and specific markets which are upstream in relation to the markets for pharmaceutical specialities. Active substances are produced from chemical and biological products and may be either manufactured for in-house purposes or traded. There are markets for active substances to the extent that such substances are the object of transactions between a producer and a buyer of these substances.

13. Future products: In the pharmaceutical industry, a full assessment of the competitive situation regularly requires examination of products which are not yet on the market, but which are at an advanced stage of development. The potential for these products to enter into competition with other products which are either at the development stage or already on the market can be assessed by reference to their characteristics and intended therapeutic use. The Commission has to look at R&D potential in terms of its importance for existing, but also for future market situations. Quite naturally, the relevant product market tends to be defined in a less clear cut manner than in the case of existing markets. Market definition will very often not be based on existing ATC classes, but primarily guided by the characteristics of future products as well as by the indication to which they are to be applied.

d) Did you find it necessary to distinguish the market for drugs consumed in hospitals from the market for drugs prescribed by physicians and/or the market for over-the-counter drugs ?

14. The Commission has recognized that a classification on ATC level 3 might be further subdivided on the basis of a variety of demand-related criteria. A possible distinction between prescription drugs and over-the-counter has been identified.[6] However, in most of the cases it was not discussed further whether these two groups constituted separate product markets because the outcome of the assessment did not depend on this.[7]

15. In some cases, parties identified separate markets for in-hospital and commodity products on the basis of the following criteria: mode of administration, products' presentation, different distribution methods (greater role of wholesalers for distribution to pharmacies), different kind of products used for hospital-acquired and community-acquired diseases. The Commission has dealt with this distinction between hospital markets and markets for drugs prescribed by physicians only in very few decisions. In *Rhône-Poulenc Cooper*,[8] the question was left open.

e) Was the relevant geographic extent of the market national or international?

16. Pharmaceutical specialities: There are Community efforts for standardisation in the pharmaceutical sector. Measures include *inter alia* the harmonisation of technical provisions within the Community and the entry into force of new registration procedures for medicines. Since the beginning of 1995, pharmaceutical companies have the option (and for biotechnology products the obligation) of submitting an application for registration of a new medicine to the European Agency for the Evaluation of Medicinal Products for a centralised authorisation procedure.[9]

17. The sale of medicines is, however, still influenced by the administrative procedures or purchasing policies which the national health authorities have introduced in the Member States. Some countries exercise a direct or indirect influence on prices, and there are different levels of reimbursement by the social security system for different categories of medicines. For this reason, the prices for medicinal

products differ from one Member State to another. In addition, there are far-reaching differences in terms of brand and pack-size strategies and in distribution systems. These differences lead to national market characteristics.

18. Active substances: In some merger decisions, the Commission has established that the upstream market for active substances is at least EEA-wide. [10]

19. Future products: Because research and development is normally global, the said national restrictions do not create the same entry barriers as for existing pharmaceuticals. The issue of future markets is therefore considered at least in terms of territory of the Community and possibly the world-wide market.

4.3 Did you consider that the pharmaceutical industry is characterised by barriers? What barrier do you identify?

20. A barrier to entry refers to a cost borne by new entrants that has not been borne (or at least not the same extent) by the incumbent market players. However, the notion of a barrier to entry into the pharmaceutical industry sometimes refers to a broader concept relating to the large investment in R&D that is necessary to develop new products. This need for a large financial effort seems to be due to the length of time required to run through the different development phases of a new product, according to a process which is partially governed by regulatory provisions.

21. Besides, large investments are also required at the level of marketing. Regulatory provisions that define categories of drugs available only by prescription lead pharmaceutical companies to devote the bulk of promotional expenditures to visits to individual physicians (so called practice of detailing). Since the level of a company's detailing activity is closely related to its size, marketing efforts play the role of an entry barrier analogous to the set up cost involved in the development of new drugs.

22. The new wave of mergers in the pharmaceutical and agrochemical industry seems to be the market response to the need for such a large financial base. Size is claimed to be an increasingly important competitive factor in the pharmaceutical industry, for it allows to leverage increasing R&D costs across a broader range of products and to spread the risk inherent in every new research project over a large capital base. Strong pharmaceutical producers therefore might not face serious problems to enter a market on which they so far have not been present. Smaller pharmaceutical companies try to overcome this difficulty by teaming up with established producers who might contribute to the R&D investment and the later marketing of the product.

23. Potential entry barriers resulting from the need to obtain market authorisation are now mitigated by the centralised authorisation procedure referred to above. This procedure enables pharmaceutical producers to acquire a single authorisation from the European Agency for the Evaluation of Medicinal Products for the entire Community.

24. Patent protection in this sector (20 years plus additional five year protection according to the Supplementary Protection Certificate) has been identified as an entry barrier in the merger decision Ciba/Geigy .[11]

4.4 Collusion

25. The OECD's question mainly refers – by implication - to horizontal forms of concertation between pharmaceutical producers (e.g. market sharing or sales quota cartels). Until now, the Commission has not had to look into this kind of practices.

26. The Commission's antitrust decisions mainly concern vertical agreements between pharmaceutical producers and their wholesalers which have as their object and/or effect to exclude or impede parallel trade (see e.g. Commission's decision in Adalat, still pending before the Court of First Instance). It is also in the public domain that the Commission is currently examining Glaxo Wellcome's pricing policy in Spain in light of its negative impact on parallel trade.

4.5 Co-operative or collaborative ventures (such as co-marketing and co-promotion agreements) seem to be an important component of the pharmaceutical industry.

a) Have you had the opportunity to examine the competitive effect of such agreements?

27. The Commission has already examined several cases of co-marketing and co-promotion in the pharmaceutical sector. Other cases are under investigation. Each case has so far been considered on its own merits. So far, the Commission's services have informally cleared all co-marketing or co-promotion agreements that have been brought to their attention.

b) What features of these agreements give rise to competition concerns?

28. The main competition concerns of these agreements derive from the fact that the original producer and the partner become active on the same geographical market, under the same (co-promotion) or under different trademarks (co-marketing).

29. As far as co-marketing is concerned, the agreement may restrict competition if both partners already manufacture substitutable products or are likely to so in the foreseeable future. Furthermore, a network of co-marketing arrangements may foreclose access to the market for third parties, i.e. newcomers or potential entrants of long duration, especially if the co-marketing partners have subscribed to non-compete obligations.

30. Co-promotion agreements are in general less restrictive than co-marketing agreements, the co-promoter not being responsible for the main elements of the contract: prices, quantities, positioning, market effort, etc.

c) Have you opposed joint research and development and/or joint marketing arrangements?

No.

31. Research & Development: these arrangements have been cleared either as being non-restrictive or in any event exemptable when they are to some extent restrictive. These agreements may restrict competition when they limit the exploitation of the results of the R&D, when there is not sufficient competition at the level of R&D itself and finally, when, as a result of the co-operation, third parties are foreclosed from access to necessary technology or R&D.

32. Co-marketing and Co-promotion: The Commission has not found restrictions of competition in most cases. In other cases, it has granted an exemption in accordance with article 81.3 after the parties had appeased its concerns.

4.6. What cases of mergers have you addressed in the pharmaceutical industry?

33. The EU merger control applies to all concentrations which have a „Community dimension". The Community dimension is given where the combined aggregate worldwide turnover of all undertakings concerned is more than 5 000 million Euro and the aggregate Community turnover of each of at least two of the undertakings concerned is more than Euro 250 million, unless each of the undertakings concerned achieves more than two thirds of its aggregate Community-wide turnover within one and the same Member State. Recently, a number of mergers have been notified to the European Commission in the pharmaceutical sector: Glaxo Wellcome/SmithKline Beecham, Pfizer/Warner Lambert, Astra/Zeneca, Hoechst/Rhòne-Poulenc, American Home Products/Monsanto etc.

In what markets were concerns over market power most focused?

34. As illustrated (see 4.2), the European Commission takes ATC classification level 3 as a starting point for its operational market definition. However, in the individual case the market might be defined in a broader or narrower way.

35. So far, mergers rarely caused competition concerns on the same relevant markets. The Commission assumes a dominant position in the pharmaceutical sector only were the parties achieve relatively high market shares, by this taking into consideration that pricing is strongly influenced by regulation or reimbursement systems. Thus, the probability that a (another) merger would create a dominant position on the same market, is fairly low (except, of course, the same company is involved).

36. Competition problems more frequently have occurred for markets were one of the merging parties has hold the gold standard for a particular drug whilst the other party would have added market share. A specific pattern, related to certain product groups, has not appeared yet. Competition problems are rather related to individual strengths of the merging companies or, more precisely, the market share overlap of the merger. It seems that mergers between international pharmaceutical companies are not directly targeted to create high market shares for particular markets (see below).

37. On the other hand, mergers have raised competition concerns in a number of markets on which only little economic interest was identified (for example shrinking markets with low and decreasing value) and only a few companies are active. New competitors are unlikely to enter the market. In these types of markets, mergers of incumbent firms may create a very strong position of the parties, not be challenged by pipeline products.

What are the primary anti-competitive effects of a merger? Have mergers been opposed on the grounds that the merging companies might be competitors in the future?

38. The increasing merger activity over the last years could be explained by the companies objective to increase their future competitiveness. Two things appear to be the most important in this context: The development of new products including the use of new methods for discovery (including biotechnology) is calling for increasing resources devoted to research and development. On the other hand a new product has to be marketed in the most effective way before the product gets off patent in order to achieve a maximum of return of investment. The combination of both, successful product development and world wide marketing, could possibly be optimised within bigger companies, bundling and targeting (more) resources to profitable activities. Thus, mergers are not anti-competitive per se: more efficient marketing and research capacities might result in new products which may enter in markets were incumbent market leaders are holding dominant positions.

39. In examination of the future effects of a merger within the pharmaceutical industry, the Commission assesses the parties products which are not yet on the market but which are at an advanced stage of development. Starting from the market situation at present the Commission examines the potential for pipeline products to enter into competition with other products, which are either at the development stage or already on the market. In relation to the long term strategies parties may have when agreeing on a merger, an analysis, only taking into account a snapshot of today's market situation (or when assessing pipeline products perhaps a future period of three years) may be considered as unsatisfactory. On the other hand it appears difficult if not impossible to predict the economic success of future products, especially if they are in early stages of development. Market shares may change quickly in this sector as long as enough companies have the capacity to develop new products and to bring them successfully on the market.

What sorts of remedies have been imposed as a condition on merger approval?

40. Merging parties most generally propose undertakings in the form of a divestment or licensing (including pipeline products) if competition concerns have been identified for specific markets. The undertakings should eliminate the market share overlap or (in cases where the parties have more than two products on the market) reduce the market share increment in order to remove competition concerns.

4.9 Abuse of dominance

What cases of abuse of dominance have you addressed?

41. As stated above in 4.1, Community competition law, including Article 82 of the EC Treaty and the caselaw based thereon, applies fully to the pharmaceutical sector.

42. There are however as yet no decisions involving abuses of dominant position by pharmaceutical companies.

Have you addressed cases of tying or predatory pricing?

43. Predatory pricing: In general terms, predatory pricing by a dominant pharmaceutical company does not appear to be a likely scenario as far as in-patent products are concerned. The pharmaceutical company holding the patent for the only product on the market will not normally seek to engage in predatory pricing to gain market share given its temporary monopoly-like position. Quite on the contrary, the patent holder will set prices at levels that enable it to recoup its R & D investments.

44. Tying: No

In what ways can a pharmaceutical firm with a dominant position reduce competition from its rivals?

45. A classic means whereby competition from rivals can be reduced is refusal to deal, including refusal to supply certain services or products. A refusal by a pharmaceutical company to supply a wholesaler or a parallel trader could in principle be abusive if the general conditions developed by the Court were met.

46. A refusal to licence patents relating to pharmaceutical products could potentially be considered in terms of national and international (for example the TRIPs Agreement) rules regarding compulsory licensing.

47. In the context of competition between pharmaceutical companies and generic producers there would, generally speaking, appear to be scope for practices whereby a dominant firm can reduce competition from its rivals. The US authorities appear to be better placed to elaborate as to the specific nature of such practices. For example, the US experience includes instances of pharmaceutical companies paying generic producers not to launch generic versions of certain drugs.

48. The Commission is however currently examining a case involving possible abuses by a dominant research-based pharmaceutical company in relation to its generic competitors. The alleged abuses relate primarily to activities before national patent offices and courts as well as to the issue of withdrawal of marketing authorisations.

NOTES

1 See judgement of the CFI in Coca-Cola Company v. Commission, T-125/97, 22.03.2000 (not yet published in the ECR) par. 82. See also Commission Notice on the definition of relevant market for the purposes of Community competition law, OJ C 372, 09.12.1997, p.5.

2 OJ C 372, 09.12.1997, p. 5.

3 Case Sanofi/Sterling Drug (IV/M.072) OJ C156, 14/06/1991, p.10; Procordia/Erbamont (IV/M.223) OJ C128, 08/05/1993, p. 5; Rhône-Poulenc/Cooper (IV/M.426) OJ C113, 23/04/1994, p.2; La Roche/Syntex (IV/M.457) OJ C178, 30/06/1994, p.15; AHP/Cynamid (IV/M.500) OJ C278, 5/10/1994, p.3; Glaxo/Wellcome (IV/M.555) OJ C065, 16/03/1995, p.3; Behringwerke AG/Armour Pharmaceutical Co. (IV/M.495) OJ C134, 1/6/1995, p.4; Hoechst/Marion Merell Dow (IV/M.587) OJ C193, 27/07/1995, p.5; Upjohn/Pharmacia (IV/M.631) OJ C294, 09/11/1995, p. 9; Ciba-Geigy/Sandoz (IV/M.737) OJ L201, 29/07/1997, p.1; Hoffman La Roche/Boehringer Mannheim (IV/M.950) OJ L234, 21/08/1998, p.14; American Home Products/Monsanto (IV/M.1229) OJ C109, 20/04/1999, p.4; Astra/Zeneca (IV/M.1403) OJ C335, 23/11/1999 p.3; Sanofi/Synthélabo (IV/M.1397) OJ C023, 27/01/2000, p.4.

4 See e.g. Hoechst/Rhône Poulenc, IV/M1378 of 09.08.1999.

5 See e.g. Ciba-Geigy/Sandoz, Decision IV/M737(footnote 3).

6 Decision IV/M.1403 - Astra Zeneca (footnote 3) par. 9. In earlier Commission decisions however, it has been noted that “within the pharmaceutical industry, it is generally considered that OTC and ethical products constitute two distinct markets, although this distinction might be blurred”. This formula used in Case IV/M72 – Sanofi/Sterling Drug (footnote 3) was not repeated in later Commission’s decisions.

7 Case IV/M464 - BMSC/UPSA of 06.09.1994, OJ L2985,at par. 11.

8 Case IV/ M426 – Rhône-Poulenc/Cooper (footnote 3), at par.16.

9 See Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products, O.J. N° L214.

10 Case No. IV/M.737-Ciba Geigy/Sandoz, Case IV/M.1229 - American Home Products/Monsanto (see footnote 3).

11 See footnote 3.