EN

Case No IV/M.631 - Upjohn / Pharmacia

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REGULATION (EEC)No 4064/89
MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 28.09.1995

PUBLIC VERSION

MERGER PROCEDURE
ARTICLE 6(1)(b) DECISION

To the notifying parties

Dear Sirs,

Subject : Case No IV/M.631 - Upjohn / Pharmacia
Notification of 28.08.1995 pursuant to Article 4 of Council Regulation No 4064/89

I. THE OPERATION

1. On the 28 August 1995, Pharmacia AB, Stockholm (Pharmacia) and The Upjohn Company, Kalamazoo, Mich. / USA (Upjohn) notified to the Commission their intention to merge into Pharmacia + Upjohn, Inc. (Newco). By means of an exchange of Upjohn shares into Newco shares after Upjohns' shareholder majority approval, Newco will be merged into Upjohn. A public offer by Newco for Pharmacia will then bring about an exchange of an aggregate approximately equal amount of newly issued Newco stock for Pharmacia shares. After completion Pharmacia and Upjohn will be 100% subsidiaries of Newco which will itself then be a company quoted on various international stock exchanges and not be subject to control by any other company.

II. THE UNDERTAKINGS CONCERNED

2. The merging companies are medium sized entities in the pharmaceutical industry, holding ranks 20 and 21 of the world's top pharma companies.

   Together, they will take 9th rank and account for about 2,5% of pharmaceutical sales worldwide and a slightly higher percentage in Europe.

3. Their business activities are basically complementary in terms of products and geographical scope. Pharmacia in pharmaceutical products (84% of Group sales) focuses on oncology, growth hormone deficiency, eye disorders and intravenous nutrition and

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generates 65% of sales in Europe against 12% in the US. Its turnover is about 2600 MECU worldwide, of which about 1600 MECU in the Community. The diagnostics business covers ca 6% and the biotechnical products ca 10% of Group sales.

Upjohn's strengths with regard to pharmaceutical products (85% of Group sales) are neurological disorders, female health, steroids, anti-inflammatories and infectious diseases. The worldwide turnover of about 2800 MECU is achieved partially in Europe (445 MECU representing 15%). About 10% of the Group sales is covered by the animal health business and about 5% by chemicals.

III. CONCENTRATION OF COMMUNITY DIMENSION

4. The merging acquisition (merger of equals) of Upjohn and Pharmacia by Newco is a concentration within the meaning of Article 3(1)b of the merger regulation. The combined worldwide turnover of the parties of about 5400 MECU exceeds 5000 MECU. The aggregate Community-wide turnover of each party also exceeds 250 MECU (Pharmacia 1590 MECU, Upjohn 445 MECU). The parties do not achieve more than two thirds of their Community wide turnover in one and the same member state (Pharmacia 21% in Italy, Upjohn 20% in Germany).

The operation has therefore a Community dimension.

IV. COMPATIBILITY WITH THE COMMON MARKET

Relevant product markets

a) Preparations

5. The notification identifies 78 different pharmaceutical product markets at the member state level, based on the 3rd-level of the internationally agreed therapeutic categories (ATC) where both parties to the concentration are active. Market data according Sec 7 and 8 Form CO have been provided on 14 affected markets where the overlapping activities will result in a combined market share of 15% or more as shown in the following table:

Relevant product markets - National Level Europe

	ATC code	Therapeutic Area	Country	Pharmacia share (%)	Upjohn share (%)	Total (%)
1.	N5C	Tranquilizers	Belgium	0.1	15.2	15.3
2.	G3D	Progestogens and combinations	Germany	1.0	16.9	17.9
3.	L2A	Cytostatic hormones	Finland	15.7	3.6	19.3
4.	A7A	Antidiarrhoeals / Antibacterials	Belgium	20.7	0.2	20.9
5.	J1C	Broad Spectrum pencillines	Spain	21.3	0.1	21.4
6.	H2A	Plain corticosteroids	Portugal	1.7	20.5	22.2
7.	N5B	Hypnotics and sedatives	Italy	1.0	21.8	22.8
8.	G3D	Progestogens and combinations	Italy	20.1	8.5	28.6
9.	N5C	Tranquilizers	Spain	3.1	27.9	31.0
10.	N5C	Tranquilizers	Norway	30.0	1.7	31.7
11.	N5C	Tranquilizers	Sweden	20.9	12.1	33.0
12.	A10B	Oral Antidiabetics	Sweden	34.4	0.1	34.5
13.	L1D	Cytostatic antibiotics	Austria	68.7	0.1	68.8
14.	H2A	Plain corticosteroids	Sweden	20.6	34.9	55.5

6. It may be necessary to carry out analysis at other ATC-levels where it is appropriate to group several categories together or to use narrower markets at the fourth level.

b) R+D / Compounds

7. Furthermore the notification indicates activities of both parties in the same R+D areas concerning active compounds:

Indication	Upjohn	Pharmacia
Solid tumors	Irinotecan (CPT-11)	9-Amino campothecin (9-A-C)
AIDS/HIV	Rescriptor	Thymoctonan
Stroke	Freedox	Kabikinase
Parkinson's	Pramipexole	Cabergoline
Depression	Fluvoxamine	Reboxetine

8. According to the Commissions' investigation the parties' activities in AIDS research of the parties are not overlapping. They actually concern different R+D markets because the Upjohn product aims at suppressing the virus itself whereas the Pharmacia compound is developed to treat a secondary bacterial complication of AIDS patients and Pharmacia is not presently doing any AIDS research at all.

9. Concerning the stroke sector the Commissions inquiry again showed that Upjohn only has R+D activities (Freedox) whereas Pharmacia in fact already markets its stroke drug Kabikinase and has no R+D activities in this field. Furthermore the products Freedox and Kabikinase represent different mechanistic approaches to the stroke treatment, therefore making vertical effects on the preparation market very unlikely.

10. Regarding the depression indication the parties have stated that Upjohn actually only copromotes Fluvoxamine, a Solvay product, without being on a Phase III-compound market. Pharmacia only has Reboxetine in Phase III, competing e.g. with Taxil (Smith Kline Beecham), Effexor (AMP), Duloxetine (Eli Lilly), Gepirone (BMS) and Fluparoxan (Glaxo). Furthermore Reboxetine is a second generation tricyclic antidepressant, whereas Prozac (Eli Lilly) holds [ ][(1)] of EU N6A - preparations markets by its third generation antidepressant. This again makes vertical affects on the preparation market highly unlikely.

11. For these reasons the relevant R+D / active compounds markets other than solid tumours and Parkinson's mentioned above will not be affected by this operation.

Relevant geographic markets

a) Preparations

12. The harmonisation of technical legislation within the Community and the entry into force on 1.1.1995 of new marketing authorization procedures for medicines represent the completion of the Single Market Programme from the point of view of scientific and technical requirements for medicines. Since the beginning of 1995 pharmaceutical companies have the option (and indeed the obligation for biotechnology products) to submit an application for authorization of new medicines to the European Medicines Evaluation Agency (AMEA), which later will make a recommendation to the Commission, whose decision is binding on all Member States.

13. The sale of medicines is influenced by the administrative or purchasing policies adopted in Member States by national health services. For example, some countries take direct or indirect measures to influence prices and there are different levels of reimbursement by the social security system for different categories of medicine. For these reasons pharmaceutical prices may differ from one Member State to another. In addition there exists widespread different branding and sizing strategies and distribution systems, which further indicate national market characteristics.

14. Therefore in this case national markets have to be assumed, in line with the Commission's previous decisions and resulting from the main market conditions mentioned above.

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b) R+D / active compounds

15. If from a pricing point of view markets in the EU remain essentially national, the situation is different with respect to R&D. From the point of view of medical Research and Development of new medicines, pharmaceutical firms compete on a wider basis and generally have world-wide R&D strategies.

Assessment

16. An examination of fourteen affected national markets shows that most of them do not pose any competitive problems with respect to market domination created by this operation. On ten affected markets the overlap is less than 5% and the combined market share not higher than 35%. On two markets significant overlaps create a combined share of around 30%. Effective competition follows from the presence of important competitors having comparable or higher market shares and from many competitors having lower shares. This is appropriate especially with respect to Tranquilizers (N5C) in Sweden and Progestogens (G3D) in Italy.

Therefore the assessment focuses on those affected product markets where the combined share is above 50% indicating possible problems of market power.

Cytostatic antibiotics in Austria (L1D)

17. On this market for cytostatic antibiotics (market volume 5 MECU) Pharmacia's significant share of 68,5% (EEA: 60% of 169 MECU) is increased by a small market share of Upjohn by this operation (0,1%). The Upjohn product is only used for treating pancreatic cancer, differentiated from and rarer than breast cancer, the indication for Pharmacia's main oncology product. The main competitor Cyanamide holds [ ][(1)] and imports cover ca. 15% of the market. Furthermore three products have been introduced in 1994, including a generic. Upjohn does not carry out any research activity in this area of cytostatica in the oncology field.

18. Therefore no significant increase of Pharmacia's market position has to be expected by the concentration that could cause domination problems in the market.

Plain corticosteroids in Sweden (H2A)

19. In the market for plain corticosteroids (market volume in the EEA ca. 355 MECU) Upjohn is active in various Member States, as France, Belgium, Netherlands, Greece and also in Norway. The market shares are significant. On the European level Pharmacia's sales are 3% and the combined market shares are less than 20% The European market leader is Hoechst having [ ][(1)]).

20. The strong domestic position of Pharmacia through its activities in Sweden create a significant overlap with Upjohn in this market, having a volume of 6 MECU. The market shares (Upjohn 34,9%, Pharmacia 20,7%) reach a combined level of about 55%. There exist

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(3) Case IV/M.587 - Hoechst / MMD, pt 13; deleted business secret, between 15 and 25%.

strong competitors having significant market shares in this product market (Glaxo [ ][1], Cyanamid [ ][1]). They show a higher growth of 7-10% per year comparing the parties 3%.

21. Furthermore Upjohn's and Pharmacia's most important products in this market (Depo-Medrol resp. Prednisolon) are not to be regarded as direct competitors in the market as they are therapeutically disparate products and it has to be taken into consideration that the Prednisolon patent has already expired.

22. Additionally informations by the Swedish Medical Products Agency say that Cyanamid's main corticosteroid Lederspan directly competes with Upjohn's Depo-Medrol.

23. Regarding the conditions for potential competition it has to be seen that plain corticosteroids with improved properties will meet a high demand. As no activities are being conducted by at either party in product and process development and Pharmacia's product is already sold as a generic by many competitors in the EEA, factors for further market entries are positive. This is true especially for a generic entrant. The distribution and marketing costs will be low and for regulatory approval a simple supplementary application referring back to the original product is sufficient.

24. In summary, effective competition will continue to exist in this market and the operation will not create or strengthen a dominant position in Plain corticosteroids (H2A) in Sweden.

Research and Development / Active compounds

25. The Commission takes the view that both parties, Pharmacia and Upjohn, are medium sized pharmaceutical companies for which the costs of maintaining research programmes and covering the implementing costs for successful products (regulatory approval) are becoming very heavy to bear. Therefore it is likely that the notified operation will actually create a joint critical mass allowing the merged entity via pooled skills and resources to be a competitive player on the worldwide R+D markets of developing and inventing active compounds and resulting pharmaceutical products. Nevertheless the Commission has conducted an investigation to exclude that R+D overlaps created by this concentration could cause competition problems.

a) Cancer - solid tumours

26. Both parties are active in solid tumours research concerning irinotecan or CPT-11 (Upjohn) and 9-amino camptothecin or 9AC (Pharmacia), both belonging to the same class of compounds. The anticipated launch for the Pharmacia compound is 2001, whereas Upjohns launch may be earlier (1996/98). However even for Phase III-compounds in the solid cancer field it is not clear whether they belong finally to the same ATC-category and so causing an overlap, or offer therapeutical alternatives without belonging to the same 3-digit-ATC-category, in the future. The Commission's investigation concludes as follows regarding the competitive conditions:

27. There are competing projects as a 9-AC compound from Glaxo-Wellcome with an expected launch in 1997, Topotecan from Smith Kline Beecham (1998), Pamatex from Glaxo Wellcome (1997) and (from a different product class) Tumodex from Zeneca (1997).

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Therefore Pharmacia's product launch will meet at least three competing products of large competitors.

28. Upjohn's CPT-11 is originated by Yakult Honsha (Japan) and licensed to Rhône-Poulenc Rorer in Europe. Upjohn is licensee for the Americas, Australia and New Zealand. Therefore it is not actually overlapping with Pharmacia's 9-AC within the EEA. Furthermore 9-AC is still subject to several years of clinical trials before its therapeutical profile is ascertained. Experience and statistics from cancer research suggest that this final therapeutic use is likely to be different to CPT-11. Therefore, even assuming that a geographical overlap might exist, the product overlap is at least not certain to happen.

29. For these reasons the notified operaton will not create or increase a dominant position in R+D of solid tumours.

b) Parkinson's Disease

30. Furthermore the parties' R+D activities overlap in Parkinson's research by the Phase III compounds of babergoline (Pharmacia) and pramipexole (Upjohn). Their expected launch will be 1997. Pramipexole is a licensed project from Boehringer Ingelheim. It's marketing rights may be lost due to a clause on change of control.

31. In total at least 12 competing products are under development by different competitors, being mainly dopanime agonists as are the parties compounds. Important "pipeline-competitors" are Noprolac (Sandoz 1995), Ropinole (Smith Kline Beecham 1996), Lazabemide and Tolcapone (Roche) and Quinerolane (Eli Lilly). On the preparation level (N4A) the five major EU-competitors are Roche ([ ][(1)]), Merck ([ ][(1)]), Britannia/Orion ([ ][(1)]), Sandoz ([ ][(1)]) and Astra Medica ([ ][(1)]), whereas Pharmacia and Upjohn have no products currently marketed for Parkinson's treatment.

32. For these reasons the notified operation will create or increase a dominant position neither on the respective R+D/compound market nor for future developments. As mentioned above there are no other fields of overlap in R+D raising competition concerns.

CONCLUSION

33. For the above reasons, the Commission has decided not to oppose the notified operation and to declare it compatible with the common market and with the functioning of the EEA Agreement. This decision is adopted in application of Article 6(1)(b) of Council Regulation No 4064/89.

For the Commission,

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