

***Case No IV/M.632 -
Rhône Poulenc Rorer /
Fisons***

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**REGULATION (EEC) No 4064/89
MERGER PROCEDURE**

Article 6(1)(b) NON-OPPOSITION
Date: 21/09/1995

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 21.09.1995

PUBLIC VERSION

MERGER PROCEDURE
ARTICLE 6(1)(b) DECISION

To the notifying parties

Dear Sirs,

Subject : Case No IV/M.632 - Rhône Poulenc Rorer / Fisons
Notification of 18 August 1995 pursuant to Article 4 of Council Regulation No 4064/89

1. On 18 August 1995 Rhône Poulenc Rorer Inc. (RPR) notified the Commission that they had made a public offer to acquire control of Fisons plc. (Fisons).
2. After examination of the notification the Commission has concluded that the notified operation falls within the scope of application of Council Regulation N 4064/89 and does not raise serious doubts as to its compatibility with the common market and with the functioning of the EEA Agreement.

I. **THE PARTIES**

3. RPR is controlled by Rhône Poulenc SA (RP) and is the human pharmaceuticals arm of Rhône Poulenc, which holds 68% of its shares. RPR is engaged in the discovery, development, manufacture and marketing of human pharmaceuticals (prescription medicines, non-prescription medicines and plasma proteins). In addition RPR makes and markets certain bulk pharmaceuticals and limited quantities of other chemicals.
4. RP's only other interest in human pharmaceuticals is through its wholly owned subsidiary Pasteur Mérieux Sérums et Vaccins whose activities are limited to vaccines and other immunological products. Neither RPR nor Fisons is involved in this area.

5. RP has four major areas of activity, bulk and fine chemicals, fibres and polymers, agro (seed protection, genetics, pesticides, insecticides, etc.) and health.
6. Fisons is currently engaged in a major reorganisation of its business activities involving the disposal of major parts of its current activities. At the time of the notification it had four main business areas:
 - Pharmaceuticals, the development, manufacture and marketing of human pharmaceuticals.
 - Scientific Instruments, an agreement to sell this business was signed on 1 March 1995 and awaits regulatory approval.
 - Horticultural, the only remaining business in this area is SCAC-Fisons S.A. in France.
 - Laboratory supplies, an agreement for the sale of the bulk of this business was signed on 29 August 1995. It is subject to shareholder and regulatory approval.

II. THE OPERATION

7. The proposed concentration consists of a public offer announced on 18 August for the entire issued share capital of Fisons. The offer is made through a wholly owned subsidiary of RPR incorporated in Delaware (USA) and formed for the purpose of making the offer.

III. COMMUNITY DIMENSION

8. The combined worldwide turnover of the parties exceeds 5.000 million ECU. The aggregate Community wide turnover of RPR exceeds 250 million ECU.
9. Fisons argues that the Commission has no jurisdiction in this case. As indicated above, it signed agreements to sell its Scientific Instruments Division on 1 March 1995 and its Laboratory supplies division on 29 August 1995. Both these agreements are conditional upon regulatory approvals to be effective. In the case of the sale of the laboratory supplies business the sale is also conditional upon approval of Fisons' shareholders. Fisons says that the turnover of these businesses should be excluded from the calculation of EU turnover because their sale is the subject of firm contracts. If this view is taken then Fisons' EU turnover, according to information provided by Fisons, would be below 250 million ECU and the operation would not have a Community dimension.
10. The Commission cannot accept this argument. At the time of the notification and of this decision the sale of Fisons' laboratory supplies business was still and remains subject to the approval of the company's shareholders and therefore its turnover must be included in the calculation of turnover for the purposes of Article 1.2 of the Merger Regulation. Fisons' turnover in the European Union exceeds 250 million ECU. Neither RPR nor Fisons achieve more than two-thirds of their turnover in one and the same Member State. The operation therefore has a Community dimension.
11. This operation is distinguished from the situation in *Air France v the Commission*⁽¹⁾ where the disposal or the cessation of certain activities were held by the Court of First Instance to be a precondition of the acquisition.

(1) Case T-3/93 Judgement of 24 March 1994

IV. **THE RELEVANT MARKETS**

A. **Relevant Product Markets**

12. The activities of RPR and Fisons overlap in the following sectors:

- Medicines
- Horticultural products

The proposed operation will also result in vertical integration in the laboratorysupplies area.

Medicines

13. Medicines can be broken down into therapeutic classes according to the Anatomical Therapeutic Classification ("ATC") which is recognized and used by the World Health Organization. This classification, previously used by the Commission,⁽¹⁾ enables medicines to be grouped according to their composition and therapeutic properties.
14. The third level classes of the ATC classification provide a grouping of medicines according to their therapeutic properties, that is, their intended use and therefore may be accepted as an operational market definition. It may be necessary, however, to carry out analyses at other levels of ATC classification where it is appropriate to group particular third level categories together or to descend to narrower classes at the fourth level. This will be the case where products from different ATC classes compete as possible treatments for a specific diagnosed medical condition.
15. Furthermore, medicines may be subdivided into different segments on the basis of different criteria which may lead to distinctions, essentially from a demand-side point of view. A distinction may be made between medicines which are subject to medical prescription ("prescription-only" medicines) and medicines which are not subject to medical prescription ("non-prescription" medicines). A distinction may also be made between medicines which are wholly or partially reimbursed under the health insurance system and medicines which are not reimbursed. These segments overlap to a certain extent. Most of "prescription only" medicines are reimbursed and most of "non-prescription" medicines are not reimbursed. Moreover, the presence of one medicine in one segment is not permanent to the extent it is linked to decisions of national authorities which can lead to switches between these segments.
16. In the pharmaceutical sector, in order to be complete a competition assessment will require scrutiny of products which are not yet on the market but which are at an advanced stage of development (normally after a very considerable investment of resources of time and money). Such products will not yet have been allocated an ATC classification and their potential to compete with other products, either in development or already on the market, can only be assessed by reference to their characteristics and intended use. In

(2) Decision IV/M.072 - Sanofi/Sterling Drug (10.6.91)
 Decision IV/M.323 - Procordia/Herbamont (20.04.93)
 Decision IV/M.426 - Rhône Poulenc/Cooper (18.04.94)
 Decision IV/M.457 - La Roche/Syntex (20.06.94)
 Decision IV/M.500 - AHP/American Cyanamid (19.09.94)
 Decision IV/M.555 - Glaxo/Wellcome (28.02.1995)

some areas, any such attempt at product market definition may be problematical (in the HIV/Aids area, for example.) One possible alternative approach to defining the markets for such products would be the diagnosis category ("ICD Code").

17. Horticultural Products

Fisons is active in three areas, lawn care, slug and weed killers and growing media. The effects of the proposed operation will be examined for these products sectors, if there are no concerns using these narrow product definitions the question of the relevant product market may be left open.

18. Laboratory Supplies

Only Fisons has a laboratory supplies so there is no overlap at the distribution level. The question of the relevant market is confirmed to the vertical aspects of the supply of certain organic and inorganic chemicals to Fisons for sale in their distribution network.

Active ingredients for Pharmaceutical

19. RP supplies bulk aspirin and paracetamol while Fisons supplies sodium cromoglycate. There is no overlap at the production level for these products, however they are used in the preparation of medicines by both RPR and Fisons.

B. Geographical Reference Market

Medicines

20. 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 as far as biotechnology products are concerned) to submit an application for authorization of new medicines to the European Medicines Evaluation Agency (EMEA), which latter will make a recommendation to the Commission, whose decision is binding on all Member States.
21. However, the geographic reference markets for the sales of medicines remain for the purposes of a competition assessment essentially national, for the following reasons.
22. 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 mechanisms (for example, there is direct price fixing (as in France, Italy or Spain), overall control of companies' profits (as in the UK) and special provisions affecting the reimbursement of the cost of drugs by the national health insurance systems (as in Germany)). In addition, there are different levels of reimbursement by the social security system for different categories of medicines. For these reasons pharmaceutical prices may differ from one Member State to another. In addition there exist widespread different branding and sizing strategies and distribution systems, which further indicate national market characteristics. stated in the Commission's previous decisions (see footnote 1). In the Notification form Rhône-Poulenc refers to the same source without taking any particular point of view on it.

23. As a result of these conditions, there are appreciable differences of the undertakings' market shares and substantial price differences for similar or identical products between neighbouring areas.
24. For the above reasons the impact of this concentration has to be assessed in relation to national markets.

Horticultural Products

25. Fisons horticultural activities are almost entirely confined to France. The proposed transaction will be examined in relation to France, the narrowest market definition. If it does not give rise to competition concerns at this level it will not give rise to difficulties at the Community or EEA level.

Laboratory supplies

26. The organic and inorganic chemicals concerned are not patent protected and may be obtained from a large number of suppliers inside and outside the Community. It is reasonable to suppose that relevant market is at least the Community.

Active Ingredients for pharmaceuticals

27. None of the compounds concerned are protected by patent and there are a large number of alternative suppliers both within and outside the Community. The products are of comparatively high value and transport costs are unlikely to be a significant hindrance to their movement over long distances. It is reasonable to assume that the market is at least the EU

V. ASSESSMENT

Pharmaceuticals

28. In the present case, there are 10 horizontal affected markets on the basis of the product and geographic markets definitions indicated above :

Other mineral supplements	A12C	France
Anticoagulants	B1B	Ireland
Diuretics	C3A	Ireland, UK
Non-narcotic Analgesics	N2B	France
Antitussives	R5D	France
Xanthines	R3B	France
Preparations for the treatment of non-specific conjunctivitis	S1G	Belgium, France, UK

Each of these markets is discussed in detail below.

Other Mineral Supplements (ATC.3 A12C)

29. This category covers all mineral supplements other than calcium and potassium. They are mainly preparations containing magnesium and would be prescribed for patients with difficulties in absorbing this element.
30. There is one affected market, France where RPR has [15-25%] to which will be added [0-5%] from Fisons. Two competitors Sanofi and Labcatal have larger market shares than the merged group, RPR/Fisons.

Injectable Anticoagulants (ATC.3 B1B)

31. The ATC.3 category B1B includes injectable anticoagulants that are used to break down potentially fatal blood clots and which are also injected before general surgery to prevent thrombosis or embolism and also products for the maintenance of intravenous lines.
32. At ATC level 3 the only affected market is Ireland where the combined RPR/Fisons operation would have a market share of [35-45%] made up of [35-45%] from RPR and [0-5%] from Fisons. However, the Fisons' product, Hepsal, may be used in Ireland only for the maintenance of intravenous lines and has no other therapeutic use, it falls into ATC level 4 category B1B1. On the other hand RPR's product "Clexane" is used for prophylaxis against deep vein thrombosis (R1B 3). These two products are not substitutable.
33. There is therefore no overlap at the ATC level 4 and the merger will not change the competitive situation in relation to the Irish market for injectable anticoagulants.

Diuretics (ATC-3 C3A)

34. This category covers a wide variety of products all of which share the therapeutic effect of causing the body to lose water by urination. The most common reason for its use is congestive heart failure.
35. Two markets are affected. Ireland where [0-5%] is added to RPR's existing [25-35%] giving a combined share of [25-35%] and the United Kingdom Fisons has [0-5%] and RPR [25-35%]. In each country there are two competitors with over 10% market shares (Leo and Servier in Ireland and Leo and Ivax in the United Kingdom).
36. In addition, in both countries there are high levels of generic prescribing and generic sales (including branded generics) now account for nearly half of the market by value. In the face of this competition both RPR and Fisons sales and market shares have fallen and are likely to continue to do so.

Non-Narcotic Analgesics (ATC-3 N2B)

37. The products in this ATC level 3 category include a number of common products for pain relief including aspirin and paracetamol when used to reduce high temperatures.
38. The only affected market is France where RPR has a market share of [15-25%]. The additional market share resulting from the merger with Fisons will be less than [0-5%].

39. Three other companies, Bristol-Meyers, Hoechst and L'Oreal Synthelabo, have market shares of between 10% and 30%. The effect of the merger on this product category will be insignificant and will not create or strengthen a dominant position.

Antitussives (ARC-3 R5D)

40. Antitussives are given to prevent or ease coughs. They are generally used for the treatment of simple coughs and are available through pharmacies without prescription.
41. France is the only horizontally affected market where RPR and Fisons have market shares of [15-25%] and [0-5%] respectively. Two other companies, Sanofi and Bouchers, have market shares above 10% and remainder of the market is widely dispersed. The effect of the merger on this product category will therefore be insignificant.

Xanthines (ATC-3 R3B)

42. These products are used to relieve bronchospasm, usually a result of asthma. They are an old class of compounds and are being replaced by newer therapies. In 1994 RPR had a [45-55%] share of the only affected market, France, to which the merger would add [0-10%] from Fisons.
43. In France the change to more modern therapies has been slower than in many other EU countries. Between 1992 and 1994 the French market declined by [5-15%] a year as French doctors moved to newer treatments.
44. As a result of supply difficulties RPR has in 1995 ceased to supply its leading xanthine, slophyllin which had a market share of [35-45%]. Although it is not possible to say to what extent other RPR or Fisons xanthines will be substituted for slophyllin it is clear that the combined share of RPR and Fisons will fall significantly. The fact that RPR could discontinue its market leading product illustrates that it does not regard this market as one which will be important for its future.
45. Both Altana and Pierre Fabre had market shares exceeding that of the remaining RPR products and one Altana had a share exceeding the aggregate of Fisons and the remaining RPR products.

Preparations for the Treatment of Non Specific Conjunctivitis (ARC-3 SAG)

46. The products in this group are generally used for the treatment of conjunctivitis, the inflammation of the membranes covering the cornea and the inside of the eyelid. The most common active ingredient is sodium cromoglycate, patented by Fisons in 1965 and which is no longer protected.

There are three affected geographical markets, France, Belgium and the United Kingdom.

France

47. In France Fisons will add [10-20%] to RPR's [5-15%] market share giving a total of [20-30%], which will be insufficient to create a dominant position for this product. Furthermore the merged companies will face competition from four companies, Martin de

Moulins, Thea, Nestlé and Chauvin Blanche, with market shares of between 10% and 20%.

Belgium

48. The merged companies will have a [30-40%] share of the Belgian market for this product, [15-25%] from RPR and [10-20%] from Fisons. Two other manufacturers have market shares of between 10% and 25% (Johnson and Johnson and Boehringer Ingelheim).
49. The RPR products are essentially eyewashes for soothing tired or irritated eyes while Fisons products act against allergies. RPR and Fisons products are at best static or declining in market share. There are two major competitors one of whom Johnson & Johnson has increased its market share in the last three years to its present level of 20%. Neither of the main competitors believe that the merger will have anticompetitive effects.

United Kingdom

50. In the United Kingdom, Fisons has a market share of [55-65%] of the supply of these products to which RPR adds a further [0-5%].
51. In 1994 products containing sodium cromoglycate were approved for non-prescription sales in the United Kingdom. As a result of this development a number of companies launched new products based on this compound for non-prescription sales. In this market it is not necessary to distinguish between prescription and non-prescription sales as the market appears to be in transition to a situation where many sufferers from conjunctivitis will purchase a non-prescription remedy in the same way as sufferers from headache purchase aspirin or paracetamol. Competition from generics is therefore increasing substantially. Fisons' market share had already fallen from [65-75%] in 1992 to [55-65%] in 1994.

Conclusion

52. The merger will not create or strengthen a dominant position for any of the above pharmaceutical products on the affected markets.

Horticultural Products

53. It is estimated that Fisons has approximately [0-10%] of the overall French market for horticultural products and that Rhône Poulenc has [25-35%]. Only the three product areas in which there is an overlap were considered, lawn care products, slug and weed killers and growing media. Only in the case of growing media where it was about [15-25%] did the combined market share exceed 15%.
54. Growing media are essentially mixtures of compost and fertilisers and present very low barriers to entry. With only [15-25%] RPR/Fisons would have insufficient market power to be able to act independently of their competitors.

Research and development

55. As Fisons has sold the bulk of its research activities to Astra it has retained only a very limited pipeline of products in development. Of these only two are in phase III or nearer

the market. These are nedocromil sodium (the active ingredient in Tilade) for use in preparations for the relief of allergy in the eyes or nose and the combination of Tilade with a Beta 2 agonist for the treatment of asthma in patients requiring both prophylactic and symptomatic products.

56. As regards Fisons' work on combining Tilade with a Beta 2 agonist RPR has no projects and no existing sales in the relevant ATC level 3 category, (R3E). At the European market level (the narrowest geographic definition of the market that can be considered for research and development) the existing combined market shares for all the ATC level 3 categories where nedocromil sodium might be used for the relief of allergies are low, less than 25% and less than 10% in all categories except preparations for the treatment of non-specific conjunctivitis, (S1G). For reasons discussed above no serious competition concerns arise for this product category on narrower geographic market definitions and there is no reason to suppose that Fisons' development work on nedocromil sodium (should it prove successful) would change that position. In addition there must be considerable uncertainty as to whether the products under development will eventually reach the market.
57. RPR has no phase III or more developed products in areas where Fisons is also active other than those in the preceding paragraphs.
58. The effect of the proposed merger in the research and development area will not therefore create or strengthen a dominant position.

Laboratory supplies

59. Fisons buys the chemicals from a wide variety of suppliers and repackages them in small quantities for laboratory use. Its total sales of such chemicals in the EU are extremely small, less than [10-30] million ECU, in relation to Rhône Poulenc's sales of bulk chemicals, in the EU, more than [1000-3000] million ECU. Furthermore Fisons' contracts for the sale of laboratory supplies business have been signed and RPR have indicated that they would not rescind the sale.
60. Even in the event that this sale is not completed the proposed operation would not put the merged companies in an artificially privileged position in relation to outlets for bulk chemicals or supplies of chemicals for distribution to laboratories etc.

Active ingredients for pharmaceuticals

61. Although RP is a major supplier of both aspirin and paracetamol the proposed operation will have a negligible effect on the market for the supply of these products as Fisons share of the market medicines incorporating these active ingredients is minute, less than [insignificant] at the EU level. the merger will not therefore in any significant way increase the tied outlets for aspirin and paracetamol available to RP.
62. Fisons is the major EU supplier of sodium cromoglycate. RPR has downstream products in ATC level 3 category S1G. however RPR's share of the EU market for S1G (including products not containing) is less than [0-10%]. In 1994 RPR's requirements for sodium cromoglycate were [0-10] kilograms insufficient to affect the market which is estimated at over [5-15] tonnes.

CONCLUSION

63. It follows from the above that the proposed concentration would not create or strengthen a dominant position as a result of which competition would be significantly impeded in the common market or in a substantial part of it.

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,