COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 05.07.1993

PUBLIC VERSION

MERGER PROCEDURE
Article 6(1) a decision

To the notifying parties

Dear Sirs,

Subject : Case No. IV/M.285 - Pasteur-Mérieux/Merck
Your notification pursuant to Article 4 of Council Regulation No. 4064/89

1. On 04.06.1993, Merck & Co. Inc. (Merck) and Pasteur-Mérieux Sérums et Vaccins (PMsv) notified to the Commission an operation under which they will organise their existing activities in the human vaccine business within a territory defined as being the EEC and EFTA in a jointly controlled company (the JV).

I. THE PARTIES

2. PMsv is a subsidiary of Institut Mérieux SA, which is in turn a subsidiary of Rhône-Poulenc, a publicly owned French group of chemical and pharmaceutical companies active worldwide. PMsv is a specialist manufacturer of human and animal vaccine products, blood proteins and other related biological products. It has its R&D and production facilities centered in France, but distributes on a worldwide basis through its sales subsidiaries in the US, Canada, South America and Asia. In addition, it is

Rue de la Loi 200, B-1049 Brussels, Belgium - Office: C158 - 5/045
Telephone: direct line (+32-2)295.92.24/296.01.83 exchange 299.11.11 . Fax: 295.01.28
Telex: COMEU B 21877 . Telegraphic address: COMEUR Brussels

an important supplier to developing countries and international agencies such as WHO and UNICEF.

3. Merck is a major US company active worldwide in pharmaceuticals. As to vaccines, Merck is only active in the development, production and distribution of human vaccines mainly in the US. It also distributes vaccines in Europe and, to a minor extent, in Australia, East Asia and some Far Eastern countries.

II. THE OPERATION

4. According to the JV Master Agreement (MA) "the business of the Joint Venture will be to facilitate the research of, oversee the development of, register, arrange for the manufacture of, distribute, market and sell vaccines, immunoglobulines, diagnostics and sera and such additional products as the partners may from time to time determine". Its scope will be limited to Western Europe. A priority of the JV shall be the development of new multivalent products (page 8, MA).

5. Prior to the operation, PMsv has mainly R&D, production and distribution of human vaccines located in the JV's territory, whereas Merck distributes vaccines in Europe mainly through third parties. As a result of the operation, PMsv will transfer to the JV the whole branch of its human vaccine business including goodwill, product registration rights, trademarks and tangible distribution assets related to this branch of activity. It will further license or sublicense to the JV the patents and know-how relating to the existing and future vaccine products.

6. The JV will not assume the liabilities pertaining to this branch of activities (§4 of PMsv Transfer Agreement). Furthermore, transfer of product registration will be subject to the possibility of parallel or co-registration to permit PMsv (or Merck) to continue to manufacture these products for sale to the JV or outside the Territory.

7. For its part, Merck will transfer to the JV exclusive ownership of the product registrations in the Territory's various states with regard to existing or future vaccine products. The transfer will be subject to the condition of co-registration mentioned above. Merck will sub-license to the JV other product rights, patents and know-how in respect of existing and future products for use in the Territory.

8. The parties will remain active in the same product markets outside the Territory dedicated to the JV. They will continue to develop, produce and sell existing JV and non-JV vaccine products outside the Territory. With regard to multivalent products funded by the JV, each parent will be granted a non-exclusive worldwide licence to use related patents and know-how outside (and in case of dissolution of the JV, inside) the Territory.

9. Merck and PMsv will remain active as distinct operators in the rest of the world, although according to the parties there is only a limited geographical overlap between their activities: PMsv has traditionally had extensive activities in the Third World through international organisation bids, while Merck is only active on a State by State basis in a number countries (mainly Australia and East Asia). On the one hand, there is a certain geographical overlap in the parties' current activities (in

particular East Asia and Far Eastern countries). On the other hand, the parties are already jointly active through another JV established in the USA which coordinates the R&D activities as regards new paediatric multivalent products and will market those products within North America.

III. COMMUNITY DIMENSION

10. Merck and Rhône-Poulenc have a combined aggregate worldwide turnover exceeding 5,000 million ECU. Both companies have a Community-wide turnover in excess of 250 million ECU but do not achieve more than two-thirds of its turnover in one and the same Member States.

IV. CONCENTRATION

11. After examination of the notification, the Commission has come to the conclusion that the notified operation is not a concentration within the meaning of Article 3(2) sub-paragraph 2 2 of Council Regulation No. 4064/89 (the Merger Regulation). It therefore does not fall within the scope of application of the Merger Regulation.

(a) Joint control

12. The JV will be set up in the form of a "Société en nom collectif" (SNC) under the French law in which the parties will each hold an equal ownership interest. The SNC assembly of partners will be composed of two voting members, one appointed by Merck and one appointed by PMsv. The SNC will be managed by a "Gérant" in the form of a French "Société Anonyme à Directoire et Conseil de Surveillance" (SA) in which each parents will have an equal shareholding. The parents will be equally represented in both the Directoire and the Conseil de Surveillance. Any decision has to be taken by unanimous approval of the members in both boards. The JV Master Agreement provides for a special procedure in cases of deadlock which does not give any preponderance to either party.

As a result, the JV will be jointly controlled by the parties.

(b) JV performing on a lasting basis all the functions of an autonomous economic entity

13. The Joint Venture through which the parties will jointly develop, manufacture and market human vaccine and related products adapted to the specific needs and requirements of Western European countries will not perform on a lasting basis all functions of an autonomic economic entity. This results from an overall assessment of the following elements:

(i) R&D

14. The parties will not transfer their vaccine related R&D activities to the JV.

The parties' R&D activities are organised on a worldwide basis while the JV's scope is limited to the Territory. It is argued that it would be impossible to isolate specific teams working only on specific tasks either between the vaccines and other products (like animal vaccines and blood products), or within the human vaccines (between the monovalent and the multivalent vaccines). For these reasons they have found it impossible to physically isolate their R&D activities by reference to the JV's scope of action.

15. In addition, it is stressed by PMsv that their blood products and vaccines R&D department does not involve more than 50 top level research workers. Thus, it is stated that a transfer of some of these officials would be an uneconomical waste of rare resources which might jeopardize the overall research activity, while the JV would not be provided with the necessary quality and quantity of research workers.

16. The JV will have access to the parties' R&D through a Development Committee created within the Joint Venture. According to the JV Master Agreement:

- the JV's Development Committee will monitor the parties' ongoing research activity as regards products currently marketed within the Territory. The Committee will recommend further appropriate development activities regarding the specific European needs.

  -As regards product at a late development stage (the pipeline products) the JV will be provided with all existing product rights in the Territory subject to retention by the originating party in order to be able "to manufacture any such pipeline product solely for sale for use outside the Territory or for sale to the Joint Venture for use within the Territory". The Committee will assemble all relevant information and decide which product will continue to be funded in the Territory. If the JV elects to commercialise such a product, it will fund and direct the post-phase II testing and post-launch development studies used to support the registration and marketing of the product in the Territory. [(1)][...].

- As regards product at an early development stage (the future pipeline products), the JV's Development Committee will select, fund, and direct those projects which meet the European market needs, be they monovalent or multivalent, in the same way as for the pipeline products. The JV will be permitted to obtain the related patents, manufacturing know-how and registration rights or licenses for these products in the Territory, subject to the same retention clause mentioned in the previous sub-paragraph.

17. Given the specificities of the vaccine sector and the limited geographic scope of the JV, there might be valid economical or technical reasons not to transfer the parties R&D activities to the JV. Nevertheless, even through the establishment of the Development Committee, the JV will not have decisive influence on every stage as regards R&D. Actually, with regard to existing products, the JV (according to the JV Master Agreement) will only have the possibility to recommend to the parents to carry on new developments. With regard to future products (according to the JV Master Agreement), although the JV might show interest in a project at an earlier stage, it will direct and fund those projects only at the late stage where a commercial decision is to be taken (post phase two stage). The Development Committee will, in fact, select and fund a project (pipeline or future pipeline) only from the "post-phase

(1) In the interests of business secrets, confidential details of the agreements have been omitted.

two" stage which is the commencement of large scale safety and efficacy clinical trials.

18. It results that decisions related to the prior research and early development stages will remain with each of the parents.

19. The parties have stated that the JV might intervene at an earlier stage thus influencing decisions taken at research or early development level. However, the agreements provide for no instrument of the JV to impose to the parents any such decision. In particular, the Master Agreement does not foresee any specific compensation or funding scheme for development costs assumed by one of the parents at such an early research stage. It only states the objective to reduce overlapping efforts in the parents' research.

20. The retention of decision power as regards early development stages might not be decisive for new multivalent vaccines combining already existing antigens, but decision power at early research stages is decisive for the development of new antigens. The ability to determine the research and basic research policy independently concerning these new antigens (which could lead either to new monovalent vaccines or be included in multivalent vaccines) is a mandatory condition for an independent current and future competitive and commercial performance of a vaccine producer. This seems to be particularly true given the fact that both parents act as suppliers of vaccine on a worldwide basis and that they will continue to a considerable extent to develop and produce vaccines separately for sale outside Europe[(2)]. It can therefore be considered that their strategic decisions on R&D will be guided by their overall business interest, and not only that of the JV.

21. Consequently, given the importance of R&D in the vaccine sector and the continued separate activities of the parents outside the scope of the JV, the degree of control of the JV over the parent's R&D cannot be considered as enabling it to act as an independent player in this sector.

(ii) <u>Production</u>

22. The parties will not transfer their production facilities to the JV. Again, this is mainly due to the fact that the object of the JV is to combine their vaccine activities only partly (i.e. for Western Europe). A complete transferral is excluded mainly because:

- they will still use their production facilities in the Territory for sales outside the Territory;

- the plants are dedicated to the production of a number of different products, manufactured in campaign, including animal vaccines and blood products;

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(2) Contrary to Commission Decision IV/M.072 - Sanofi/Sterling Drug.

- it is very difficult to build new plant or remove existing production to other plants. The parties argue that vaccines can only be replicated safely in a specific manufacturing milieu which implies the use of production method, manpower skills and managerial systems whose transfer is difficult and could affect product characteristics. In addition, the new plant would have to be qualified by the relevant regulatory authority what might be very long and costly. [(3)][...]

23. As a result, according to the parties, any fragmentation of manufacturing facilities would be uneconomical and could prejudice, or at least significantly delay, the securing of the necessary authorisation from the various regulatory authorities.

24. In order to ensure the necessary JV access to manufacturing facilities, the parties entered into a number of agreements :

- Both parties will be committed to meet the JV's requirements of vaccines for its sales activity in the Territory on the basis of semi-annual production manufacturing plans established by the JV. A special procedure is established as regards exceptional demand or shortfall (pro rata delivery). The vaccine components to be included in the JV's multivalent products will be supplied by the parents subject to the same conditions.

- PMsv and, if necessary, Merck will toll manufacture the multivalent products containing components from both parties for a fee covering their costs. The JV will have the right to audit the parties costs in order to ensure that such costs are reasonable and will not adversely affect the JV's business. Following such audit, the JV may, subject to certain conditions, decide to procure manufacturing services from the other party or from any third party.

25. The Toll Manufacturing and Supply Agreements will not provide the JV with a sufficient autonomy at production level.

Firstly, no reservation of capacity which could contribute to the autonomy of the JV in respect to manufacturing,will be created to the benefit of the JV.

Secondly, the economic and contractual framework will seriously limit the possibility of the JV to exercise an autonomous sourcing and manufacturing policy.

The specific requirements related to the manufacturing of vaccines (i.e. qualification of plants by the regulatory authorities, complexity of the manufacturing process, equivalence of the product with the originally registered product) limit to a significant extent the economical alternatives for the JV to shift production given the small number of companies having such production facilities. In the notification, the parties themselves state that, from a financial and technical point of view, the only

(3) In the interests of business secrets, confidential details of the agreements have been omitted.

effective means of producing antigens for the JV's vaccines would be the continued use by the JV of the parties previously approved and well-established facilities.

According to the Toll Manufacturing and Supply Agreements the JV will have the right to audit the costs charged by each of the parents. The JV may then procure its supply services from the other parent or a third party only if these costs are considered to be unreasonable. Even in this case, such a shift would only be permitted to the extent that these services could be procured on terms which are substantially more advantageous than those the original supplying party is willing to match.

26. Consequently, on a long term basis, the JV will depend widely for its business on facilities that remain economically integrated with the parents' businesses. In addition, the JV's restricted ability to source elsewhere makes it more difficult for it to act as an independent buyer in the market.

(iii) Intangible assets

27. Neither Merck nor Mérieux will transfer its respective patents and know-how related to existing products to the JV. Access to the intellectual property will be restricted for confidentiality reasons. The JV will be granted a licence until [4][...] which can be terminated [5][...].

28. As to future parents' products selected and funded by the JV, the latter will obtain patent rights and know-how only to the extent that it does not prevent the parents from manufacturing the products for sale to the JV or for sale outside the Territory. In any event, the parent engaged in the relevant development activities will own the intellectual property rights outside the Territory. As to JV multivalent products, each parent will be granted a worldwide licence to use outside (and in case of dissolution of the JV, inside) the Territory. As a result, the whole structure of the agreements would enable the parties to operate again very quickly as independent operators in case of mutual dissolution of the JV.

(iv) Distribution

29. PMsv will transfer to the JV the share capital of all its existing sales subsidiaries active in the Territory. These subsidiaries including all employees, real property, leaseholds and distribution facilities will thus be owned and controlled by the JV.

Merck will not transfer any tangible asset to the JV but the latter will continue, where possible, the existing relationship with Merck's distributors. [6][...].

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(4) In the interests of business secrets, the time period of the licence has been omitted.

(5) In the interests of business secrets, confidential details of the agreements have been omitted.

(6) In the interests of business secrets, confidential details of the agreements have been omitted.

Consequently, the JV will take over the current and future vaccine product distribution in the Territory.

V. CONCLUSION

30. The JV will not perform all the functions of an autonomous economic entity on a lasting basis.

31. Taking into account the considerations presented above, and even considering the specificities of the vaccine market, the JV will not be in the position to take autonomous decisions related to some of the key areas in the vaccine business (i.e. R&D and production). In particular, the JV has neither physical nor financial control over the early decision regarding the research and the first development phase of new antigens which are of a strategic importance for the future competition in the market. The same applies to new development on existing product markets by the JV. Furthermore the JV would have no realistic possibility to perform an autonomous sourcing policy given the economic and legal framework set out under point 15. In addition, the Joint Venture will, to a large extent, not own intellectual property rights related to the products it distributes. Finally, the parties' main operators in the market perform the full range of the key activities mentioned above in the vaccine sector.

32. Therefore the proposed operation does not constitute a concentration in the meaning of Article 3(2) of the Merger Regulation.

33. Thus, in light of the above, the Commission has concluded that the notified operation does not fall within the scope of Council Regulation No. 4064/89. This decision is adopted under Article 6, paragraph 1)(a) of the above-mentioned Regulation.

For the Commission