EUROPEAN COMMISSION
DG Competition

Case M.9554 - ELANCO ANIMAL HEALTH / BAYER ANIMAL HEALTH DIVISION

Only the English text is available and authentic.

REGULATION (EC) No 139/2004
MERGER PROCEDURE

Decision on the implementation of the commitments - Purchaser approval
Date: 05/02/2021

EUROPEAN COMMISSION

Brussels, 5.2.2021
C(2021) 918 final

PUBLIC VERSION

In the published version of this decision, some information has been omitted pursuant to Article 17(2) of Council Regulation (EC) No 139/2004 concerning non-disclosure of business secrets and other confidential information. The omissions are shown thus […]. Where possible the information omitted has been replaced by ranges of figures or a general description.

Elanco Animal Health Inc.
2500 Innovation Way
46140 Greenfield, Indiana
United States of America

Dear Sir or Madam,

Subject: Case M.9554 - Elanco Animal Health/Bayer Animal Health Division
Approval of Virbac as purchaser of the ESP Divestment Business following your letter of 4.12.2020 and the Trustee's opinion of 21.01.2021

1. FACTS AND PROCEDURE

(1) By decision of 8 June 2020 (the "Decision") based on Article 6(1)(b) in conjunction with Article 6(2) of Council Regulation (EC) No 139/2004[1] and Article 57 of the EEA Agreement, the Commission declared the operation by which Elanco Animal Health Inc. ("Elanco", USA) acquires sole control of Bayer AG's ("Bayer", Germany) animal health business ("BAH", together with Elanco the "Parties") (the "Transaction") compatible with the internal market and the EEA agreement. The

[1] OJ L 24, 29.1.2004, p. 1 (the "Merger Regulation").

Decision is subject to the conditions and obligations laid down in the commitments annexed to the Decision. The commitments consist of two components, *i.e.* the "Main Commitments" and the "Additional Commitments", all together referred as the "Commitments".

(2) In particular, under the Main Commitments, the Parties undertook to divest to suitable buyers the following products:

a. Elanco's VECOXAN (anticoccidials for ruminants) at global level (the "Anticoccidials Divestment Business");

b. Elanco's OSURNIA (long lasting otitis treatment) at global level, including two pipelines (the "Otitis Divestment Business"); and

c. BAH's Drontal and Profender family of products (endoparasiticides for companion animals) at EEA level (the "Endoparasiticides Assets") and the pipeline product based on the […] compound (endectocide for cats) at global level (the "[…] Pipeline" or the "Endectocide Assets") (together referred as the "Parasiticides Divestment Business").[2]

(3) Under the Additional Commitments, the Parties undertook to divest either (i) BAH's pipeline products based on the […] compound[3] at global level (the "[…] Pipelines" or the "ESP Divestment Business") or, alternatively, (ii) Elanco's marketed and pipeline isox products based on the Lotilaner compound at EEA level (the "Alternative Divestment Business"). The transfer of the pipeline products included in the ESP Divestment Business is subject to the consent of […], which is licensing the […] compound to BAH.

(4) This decision only concerns the approval of the proposed purchaser of the ESP Divestment Business.[4]

(5) On 27 November 2020, Elanco and Virbac S.A. ("Virbac" or the "Proposed Purchaser") entered into the Asset Purchase Agreement for the sale of the ESP Divestment Business. On 8 December 2020, the Parties, Virbac and […] entered into the Memorandum of Understanding related to the Revised Licensed Agreement agreed between Virbac and […]. The above agreements cover the divestiture of the entirety of the ESP Divestment Business. Together with their respective schedules, they are hereinafter referred to as the "Transaction Agreements".

(6) By reasoned submission dated 4 December 2020, Elanco proposed Virbac for approval by the Commission as purchaser of the ESP Divestment Business. Virbac is a publicly listed animal health company that develops, manufactures and sells

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2 By decisions of 9 July 2020, the Commission approved Merck & Co, Inc. (Kenilworth, New Jersey, USA) ("MSD") as purchaser of the Anticoccidials Divestment Business and Dechra Pharmaceuticals PLC ("Dechra") as purchaser of the Otitis Divestment Business. By decision of 20 July 2020, the Commission approved Vetoquinol S.A. ("Vetoquinol") as purchaser of the Parasiticides Divestment Business.

3 Namely B-00010535 (oral canine ecto product); B-00010571 (topical feline ecto product) and B-00010601 (topical canine ecto product).

4 Capitalised terms in this decision will have the meaning as set out in the Additional Commitments, unless indicated otherwise.

veterinary pharmaceuticals and vaccines on a global basis. The company, which was founded in 1968 and is headquartered in Carros (France), is the sixth largest animal health player globally. Virbac has a direct presence via its subsidiaries in 34 countries and markets its products in approximately 100 countries via third-party distributors. At the end of 2020, Virbac employed nearly 4 900 employees worldwide. Virbac's worldwide revenues in 2019 amounted to EUR 938 million.

(7) In its opinion of 21 January 2021 (the "Reasoned Opinion"), pursuant to paragraph 42(viii) of the Additional Commitments, Monitoring Trustee Partners, acting as monitoring trustee (the "Trustee"), concludes that:

(a) Virbac fulfils the Purchaser Criteria as set out in section E of the Additional Commitments and that there is no indication that the ESP Divestment Business would not be viable after the sale; and

(b) the ESP Divestment Business would be sold in a manner consistent with the Additional Commitments under the Transaction Agreements.

2. ASSESSMENT OF THE PROPOSED PURCHASER

(8) According to paragraph 32 of the Additional Commitments, in its assessment of the Transaction Agreements, the Commission has to verify that the Purchaser fulfils the Purchaser Criteria and that the ESP Divestment Business is being sold in a manner consistent with the Additional Commitments including their objective to bring about a lasting structural change in the market.

2.1. Assessment of the Purchaser criteria

(9) As set out in paragraph 31 of the Additional Commitments, in order to be approved by the Commission, the Purchaser of the ESP Divestment Business must fulfil the following criteria:

(a) The Purchaser shall be independent of and unconnected to Elanco and BAH and their Affiliated Undertakings (this being assessed having regard to the situation following the divestiture);

(b) The Purchaser shall have the financial resources, proven expertise and incentive to maintain and develop the ESP Divestment Business as a viable and active competitive force in competition with the Parties and other competitors;

(c) The acquisition of the ESP Divestment Business by the Purchaser must neither be likely to create, in light of the information available to the Commission, *prima facie* competition concerns nor give rise to a risk that the implementation of the Additional Commitments will be delayed. In particular, the Purchaser must reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the ESP Divestment Business; and

(d) The Purchaser shall have:

– Established capabilities or a track record in the clinical development of animal health products in the EEA/UK, including with regard to having interactions with relevant EEA-wide and national bodies that decide on approval of animal health products;

– Established capabilities or a track record in the manufacture, commercialisation and distribution of animal health products in the EEA/UK;

– Sufficient R&D resources and experience to develop the relevant pipeline products included in the scope of the ESP Divestment Business; and

– Complementary products and expertise relevant to the ESP Divestment Business.

2.1.1. Independence from the Parties

(10) *First*, the Trustee's review of the relationships between the Parties and Virbac did not reveal any significant corporate or structural link. Virbac is publicly listed on the Euronext Paris Stock Exchange. Its main shareholder (holding a share of 49.5% and 63.2% of the voting rights), namely Investec, is a private company owned by the members of the Dick family. No other shareholder directly owns more than 3% of Virbac's shares. The Parties do not hold directly or indirectly any shares in Virbac or Investec. Moreover, there is no material common shareholding between Virbac and the Parties and none of the members of the Parties' boards of directors is at the same time a member of the board of directors of Virbac or Investec.[5]

(11) *Second*, while there are a few existing business relations and contractual relations between Virbac and the Parties, the Trustee's review has shown that any agreements between them are (i) common industry practice and (ii) limited in terms of financial scope (representing less than [...]% of Virbac's global revenues in 2019). In view of the foregoing, the Trustee concludes that these agreements do not impede the independence of Virbac from the Parties.[6]

(12) In light of the above, the Commission considers that Virbac is independent of and unconnected to Elanco and BAH and their Affiliated Undertakings.

2.1.2. Financial resources, proven expertise and incentive to maintain and develop the ESP Divestment Business as a viable and active competitor

2.1.2.1. Financial resources

(13) *First*, as regards Virbac's financial resources, the Commission notes that the company has a market capitalisation of approximately EUR 1.8 billion (as of 3 December 2020). In 2019, it generated revenues of EUR 938 million (+8% compared to the prior year), with an EBITDA of EUR 149 million and net income of EUR 52 million. The Trustee's analysis of Virbac's financial documentation shows a

5 Reasoned Opinion, Section 4.2.

6 Reasoned Opinion, Section 4.3.

strong balance sheet with significant cash balance. In view of the foregoing, the Trustee concluded that Virbac has sufficient financial resources to develop the ESP Divestment Business going forward.[7]

(14) *Second*, under the Transaction Agreements, Elanco will reimburse and compensate part of the expenses incurred by Virbac for the development of the ESP Divestment Business. The funding contributed by Elanco will increase Virbac's resources to develop the […] Pipelines, therefore financially de-risking the development of the ESP Divestment Business. Virbac will fund the remaining costs of development through its existing cash resources, […].

(15) Based on the information above and the Trustee's Reasoned Opinion on the financial situation of Virbac, the Commission concludes that Virbac fulfils the criterion of having the financial resources to maintain and develop the ESP Divestment Business as a viable and active competitive force in competition with the Parties and other competitors.

2.1.2.2. Proven expertise

(16) According to paragraph 31 of the Additional Commitments, the Proposed Purchaser must have the proven expertise to maintain and develop the ESP Divestment Business as a viable and active competitive force in competition with the Parties and other competitors.

(17) In this respect, the Commission considers, in line with the Reasoned Opinion,[8] that Virbac has a deep understanding of the ESP Divestment Business, as it is already active in the parasiticides markets. Virbac is indeed an established animal health company, operating globally, with a significant footprint in the EEA. Founded in 1968, the company has a long history in this sector. It develops, manufactures and markets a large number of veterinary products for companion animals, including parasiticides. Moreover, the Reasoned Opinion points out that Virbac has relevant experience in acquiring and integrating pipeline assets into its organisation (such as Suprelorin in 2011).[9]

(18) Furthermore, according to paragraph 31 of the Additional Commitments, the Proposed Purchaser shall have sufficient R&D resources and experience to develop the relevant pipeline products, as well as established capabilities or a track- record in the clinical development of animal health products in the EEA/UK. Moreover, the Proposed Purchaser shall have established capabilities or a track record in the manufacture, commercialisation and distribution of animal health products in the EEA/UK. Finally, the Proposed Purchaser shall have complementary products and expertise relevant to the ESP Divestment Business.

(a) Sufficient R&D Resources and Experience

7 Reasoned Opinion, Section 5.2.

8 Reasoned Opinion, Section 5.3.

9 Reasoned Opinion, Section 7.1.8.

(19) It appears from the Trustee's Reasoned Opinion[10] that the R&D capabilities of Virbac are material. The company has eight R&D facilities worldwide (the main one being located in France) covering all aspects related to animal health pharmaceutical product development, including for parasiticides. Moreover, Virbac has a large number of employees working in the field of R&D worldwide, many projects currently under development and R&D expenditure of EUR 75 million in 2019 (*i.e.* around 8% of its annual revenues).

(20) Based on the above considerations and the Trustee's Reasoned Opinion, the Commission concludes that Virbac's R&D resources and experience are sufficient to finalise the development of the […] Pipelines.

(b) Clinical Development Capabilities in the EEA/UK

(21) *First*, the Trustee observes that the vast majority of Virbac's total product range consists of originator and innovative products developed internally. In fact, Virbac is currently developing several original or innovative animal health products based on new chemical entities or innovative formulation technologies, many of them being at the same stage of development or more advanced than the […] Pipelines.

(22) *Second*, Virbac has a large and dedicated team of employees working on European regulatory affairs, having experience in dealing with relevant national and supranational regulatory bodies to obtain marketing authorisations and launch new products in the EEA/UK. During the last few years, Virbac has successfully processed a number of product approvals in the EEA/UK.[11]

(23) Based on the above consideration and the Trustee's Reasoned Opinion, the Commission considers that Virbac has established capabilities in the clinical development of animal health products in the EEA/UK, including with regard to having interactions with relevant EEA-wide and national bodies that decide on approval of animal health products in the EEA/UK.

(c) Manufacturing, commercialisation and distribution capabilities in the EEA/UK

(24) *First*, the Commission notes that Virbac has significant in-house manufacturing capability, with 17 production sites worldwide, three of them being located in the EEA/UK (including Virbac's largest manufacturing facility in France). Moreover, Virbac also has extensive experience in outsourcing parts of its production to contract manufacturing organisations ("CMOs"), which is common practice in the industry.[12]

(25) *Second*, Virbac is directly present through affiliates in the main animal health markets in the EEA/UK, and through distributors in the other EEA/UK countries where it does not have a direct presence. The Reasoned Opinion observes that Virbac has a well-established marketing and distribution network, with a significant number of sales and marketing employees throughout the EEA/UK. Virbac markets

10 Reasoned Opinion, Section 5.3.2.

11 Reasoned Opinion, Section 5.3.2.

12 Reasoned Opinion, Section 5.3.3.

a large number of products in the EEA/UK, which allows it to reach a share of around [5-10]% in animal health products for companion animals at EEA/UK level.[13] In 2019, Virbac's revenues in the EEA represented a large share of its global sales.[14]

(26) Based on the information above and the Trustee's Reasoned Opinion, the Commission considers that Virbac has the manufacturing, commercialisation and distribution capabilities to maintain and develop the ESP Divestment Business.

(d) Complementary products and expertise relevant to the ESP Divestment Business

(27) The Reasoned Opinion emphasises that Virbac has a significant product portfolio in companion animals, which accounts for a large share of the company's total revenues. In particular, Virbac markets various parasiticides for dogs and cats, including ectoparasiticides (such as Effipro/Effitix products) in the EEA/UK.[15] However, Virbac does not market any isox-based parasiticides, *i.e.* the newest chemical class of ectoparasiticides, which the […] Pipelines belong to.[16] In this context, the ESP Divestment Business appears highly complementary to Virbac's companion animal product portfolio as it will enable the company to enter the rapidly increasing isox market segments with very competitive products[17] and to offer a more complete range of products to its companion animal customers in the EEA/UK.

(28) Based on the information above and the Trustee's Reasoned Opinion, the Commission considers that Virbac has sufficient complementary products and expertise relevant to the ESP Divestment Business.

2.1.2.3. Incentives to maintain and develop the ESP Divestment Business

(29) As regards Virbac's incentives, the Trustee considers that the acquisition of the ESP Divestment Business will enhance and accelerate Virbac's presence in the companion animal parasiticides markets, by adding pipelines of isox-based products. The acquisition of the […] Pipelines will give Virbac the opportunity to launch potentially leading and innovative ecto products for cats and dogs[18] and allow it to compete with animal health companies that already have isox-based products in their portfolio.[19]

(30) The Trustee also observes that Virbac's projections for the ESP Divestment Business […] appear reasonable. The Commission also notes that, even under Virbac's conservative forecasts, the ESP Divestment Business is expected to be […] profitable. Therefore, the Commission considers that the ESP Divestment Business

13 Source: Parties' estimates (see Annex 6 to the Form CO).
14 Reasoned Opinion, Section 5.3.4.
15 Reasoned Opinion, Section 5.3.5.
16 See notably Decision, paragraphs 29 and 131.
17 See Decision, paragraph 151.
18 See Decision, paragraph 151.
19 Reasoned Opinion, Section 5.4.

constitutes an attractive investment and strategic opportunity for Virbac, which will thus be highly incentivised to ensure the success of the acquired business.[20]

(31) Based on the information above and the Trustee's Reasoned Opinion, the Commission considers that Virbac has the incentives to maintain and develop the ESP Divestment Business.

2.1.3. Absence of prima facie competition problems and implementation risks

(32) *First*, as explained in Section 2.1.2(d) above, the ESP Divestment Business is highly complementary with Virbac's existing product portfolio. The latter does not market any isox-based parasiticides and does not have any pipeline products expected to compete with the ESP Divestment Business in the coming year.[21]

(33) *Second*, the Commission notes that […] has already approved the transfer of the ESP Divestment Business to Virbac and found an agreement with Virbac on the terms of the licence for the […] compound.[22] No other third-party consent is required.

(34) *Third*, the acquisition of the ESP Divestment Business by Virbac will not trigger merger control filings in the EEA or in other jurisdictions.[23]

(35) In light of the above, the Commission considers, in line with the Trustee's Reasoned Opinion, that the acquisition of the ESP Divestment Business by Virbac is neither likely to create *prima facie* competition concerns, nor to give rise to a risk that the implementation of the Additional Commitments will be delayed.

2.1.4. Conclusion

(36) In view of the foregoing, the Commission concludes that Virbac meets the Purchaser Criteria as set out in paragraph 31 of the Additional Commitments.

2.2. The ESP Divestment business is being sold in a manner consistent with the Additional Commitments

(37) There are a few minor deviations between the Additional Commitments and the Transaction Agreements, which are summarised below:

(i) *Duration of transition arrangements*: Schedule 1 to the Additional Commitments defines the duration of all transitional services arrangements relating to the ESP Divestment Business uniformly as twelve months (renewable once), while the Transaction Agreements define the duration of the transitional supply arrangements for each activity separately and differently (without exceeding for any of the arrangements the twelve-month duration set forth in the Additional Commitments). The Trustee has reviewed the duration of the transitional supply arrangements and finds it suitable.

20 Reasoned Opinion, Section 7.1.
21 Reasoned Opinion, Section 5.5.
22 See paragraph 3 above.
23 Reasoned Opinion, Section 5.5.

Virbac confirmed that it is satisfied with the arrangements.[24] The Commission also considers the duration of the transitional supply arrangements to be reasonable; and

(ii) *Key Personnel*: under Schedule 1 to the Additional Commitments, the ESP Divestment Business includes the transfer of the Key Personnel (consisting of nine individuals). However, under the Transaction Agreements, such transfer is at the option of Virbac (until closing). Virbac already indicated that it does not envisage the need to exert the above option, explaining that the company already has in-house the relevant functions and providing details on the allocation of the individuals that would replace the Key Personnel and their relevant experience. In light of Virbac's explanations, as well as its overall R&D and clinical development capabilities,[25] the Trustee and the Hold Separate Manager deem that the set-up and the qualifications of the individuals that will replace the Key Personnel will ensure a smooth continuation of the development of the ESP Divestment Business after the sale.

(38) In light of the above, the Commission considers that the above deviations do not affect in any way the viability and competitiveness of the ESP Divestment Business after the sale. Therefore, the Commission concludes that the ESP Divestment Business is being sold in a manner consistent with the Additional Commitments including their objective to bring about a lasting structural change in the market.

3. CONCLUSION

(39) On the basis of the above assessment, the Commission approves Virbac as a suitable purchaser of the ESP Divestment Business.

(40) On the basis of the Transaction Agreements, the Commission further concludes that the ESP Divestment Business is being sold in a manner consistent with the Additional Commitments.

(41) The present decision only constitutes approval of the Proposed Purchaser identified herein and of the Transaction Agreements. This decision does not constitute a confirmation that the Parties have complied with the Additional Commitments.

(42) The present decision is based on paragraph 32 of the Additional Commitments attached to the Decision of 8 June 2020.

For the Commission

(Signed)
Olivier GUERSENT
Director-General

[24] Reasoned Opinion, Section 6.4.

[25] See above Section 2.1.2.2(a) and (b).