



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
MERCER PROCEDURE**

Decision on the implementation of the commitments -
Purchaser approval

Date: 09/07/2020



EUROPEAN COMMISSION

Brussels, 09.07.2020
C(2020) 4815 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 Where possible the information omitted has been replaced by ranges of figures or a general description.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/Madam,

Subject: Case M.9554 – Elanco Animal Health/Bayer Animal Health Division Approval of Dechra as purchaser of the Otitis Divestment Business following your letter of 10.06.2020 and the Trustee’s opinion of 24.06.2020

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 139/2004¹ 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”) (the “Transaction”) compatible with the internal market and the EEA Agreement. The 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

¹ OJ L 24, 29.1.2004, p. 1 (the “Merger Regulation”).

“Additional Commitments”, all together referred as “the Commitments”. Elanco and BAH are hereinafter collectively referred to as the “Parties”.

- (2) In particular, under the Main Commitments, the Parties undertook to divest to suitable buyers the following products:
 - a. Elanco’s VECOXAN (anticoagulants for ruminants) at global level (the “Anticoagulants Divestment Business”);
 - b. Elanco’s OSURNIA (long lasting otitis treatment) at global level [...]² (the “Otitis Divestment Business”); and
 - c. BAH’s Drontal and Profender family of products (CA endoparasiticides) at EEA level and the pipeline product based on the [...] compound (the “[...] Pipeline”) (the “Parasiticides Divestment Business”).
- (3) Under the Additional Commitments, the Parties undertook to divest either (i) BAH’s pipeline products based on the [...] compound at global level (the “[...] Pipelines”) or, alternatively, (ii) Elanco’s marketed and pipeline isox products based on the [...] compounds at EEA level (the “Alternative Divestment Business”).
- (4) This decision only concerns the approval of the proposed purchaser of the Otitis Divestment Business.
- (5) By a reasoned submission dated 10 June 2020, Elanco proposed Dechra Limited and Dechra Veterinary Products LLC (which are subsidiaries of Dechra Pharmaceuticals PLC, “Dechra”) for approval by the Commission as purchaser of the Otitis Divestment Business. Dechra develops, manufactures, markets, and sells veterinary pharmaceuticals and related products for veterinarians worldwide. Dechra supplies various veterinary pharmaceutical products, including endocrinology, dermatology, analgesia and anesthesia, antibiotic, cardiovascular, and critical care products for dogs and cats; water soluble antibiotics, poultry vaccines, locomotion, and pain management products for poultry, pigs, and cattle; and lameness and pain management products for horses and ponies. It also provides pet nutrition products for supporting cats and dogs with various therapeutic conditions, such as allergies, obesity, heart, and kidney diseases. It markets its products through wholesaler and distributor networks.
- (6) Elanco submitted to the Commission the agreements to be entered into between Elanco and Dechra, consisting of the asset purchase agreement (the “Asset Purchase Agreement”) together with the schedules and exhibits (all together the “Transaction Agreements”).
- (7) In its opinion of 24 June 2020 (the “Reasoned Opinion”) pursuant to paragraph 32 (viii) of the Main Commitments, Monitoring Trustee Partners, acting as monitoring trustee (“the Trustee”), concludes that:
 - a. Dechra fulfils the Purchaser Criteria as set out in paragraph 21 of the Main Commitments and there are no indications that the Otitis Divestment Business would not be viable after the sale; and

² [...].

- b. the Otitis Divestment Business would be sold in a manner consistent with the Main Commitments under the Transaction Agreements.

2. ASSESSMENT OF THE PROPOSAL

- (8) According to paragraph 22 of the Main Commitments, in its assessment of the Transaction Agreements, the Commission has to verify that the purchaser fulfils the Purchaser Criteria and that the Divestment Business is being sold in a manner consistent with the 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 21 of the Main Commitments, the purchaser of the Divestment Business³ must fulfil the following criteria:
 - (a) The Purchaser(s) 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(s) shall have the financial resources, proven expertise and incentive to maintain and develop the Divestment Businesses as a viable and active competitive force in competition with the Parties and other competitors;
 - (c) The acquisition of the Divestment Businesses by the Purchaser(s) 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 Commitments will be delayed. In particular, the Purchaser(s) must reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Divestment Businesses; and
 - (d) The Purchaser(s) shall have:
 - i. Established capabilities or a track record in the manufacture, marketing and distribution of animal health products in the EEA/UK;
 - ii. Adequate manufacturing and regulatory capabilities to successfully implement a production transfer in relation to the Divestment Businesses (where relevant);
 - iii. Sufficient R&D resources and experience to develop the relevant pipeline products included in the scope of the Divestment Business(es); and
 - iv. Complementary products and expertise relevant to the Divestment Businesses.

³ Capitalised terms in this decision will have the meaning as set out in the Commitments, unless indicated otherwise.

2.1.1. *Independence from Elanco and BAH*

- (10) Dechra, Elanco and BAH are publicly traded. Dechra is listed on the London Stock Exchange. Elanco is listed on the New York Stock Exchange, and Bayer is listed on a number of stock exchanges in Germany (Berlin, Düsseldorf, Frankfurt, Hamburg, Hannover, Munich and Stuttgart). Elanco or BAH do not hold directly any controlling shareholding on Dechra. Therefore, Dechra is neither owned nor controlled by Elanco, BAH or any of their affiliates.⁴ Three of the larger investors in Elanco also hold interests in Dechra (being The Vanguard Group, Inc., Black Rock Inc. and Norges Bank Investment Management), and also three of the larger investors in Bayer hold interests in Dechra (being FMR LLC, The Vanguard Group, Inc. and Norges Bank Investment Management). The Trustee considers, however, that these shareholdings are relatively small (the largest ones, from a Dechra perspective, being FMR LLC, Black Rock Inc., Inc., and The Vanguard Group, with a 9.7%, a 5.0% and a 4.0% stake respectively) and, therefore, do not lead to a control situation by any of the shareholders.
- (11) No director of any of Elanco or BAH serves on the board of Dechra or any of its affiliates and *vice versa*.⁵
- (12) The Trustee also reviewed the existing business relations and contractual relations between Dechra and the Parties and concluded that they do not appear to be material to any party.⁶ Commercial relationships are limited and represent less than [...] % of Dechra's annual revenues in 2019⁷.
- (13) In light of the above, the Commission concludes that Dechra fulfils the purchaser criterion of being 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 Otitis Divestment Business as a viable and active competitor*

2.1.2.1. Financial resources

- (14) The market value of Dechra's equity amounted to EUR 3.3 billion as per May 31, 2020. In 2019, Dechra had a turnover of EUR 549.5 million.
- (15) The Trustee reviewed the financial results of Dechra and concluded that Dechra is a healthy and profitable business that has achieved steady growth while maintaining a sound solvency position. The company's net interest-bearing debt position is comfortable and, hence, Dechra has a strong potential to attract further debt financing if and when needed.⁸
- (16) Dechra will pay EUR 121.5 million for the Otitis Divestment Business. The Trustee considers that Dechra has multiple significant sources to fund the acquisition and the

⁴ Monitoring Trustee Reasoned Opinion on the acquisition of the Otitis Divestment Business by Dechra of 24 June 2020 ("Reasoned Opinion"), Section 4.

⁵ Reasoned Opinion, Section 4.

⁶ Reasoned Opinion, Section 4.

⁷ Reasoned Opinion, Section 4.

⁸ Reasoned Opinion, Section 5.

subsequent development of the Otitis Divestment Business, owing to the company's current and expected capability to generate significant positive operating cash flows as evidenced by its EBITDA performance as well as its additional loan capacity as evidenced by its strong balance sheet.⁹

- (17) Based on the information above and the Trustee's Reasoned Opinion¹⁰ on the financial situation of Dechra and the business plan for the acquisition of the Otitis Divestment Business, the Commission concludes that Dechra fulfils the criterion of having the financial resources to maintain and develop the Otitis Divestment Business as a viable and active competitive force in competition with Elanco and other competitors.

2.1.2.2. Proven experience

- (18) According to paragraph 21 of the Main Commitments, the Proposed Purchaser must have the proven expertise to maintain and develop the Divestment Business as a viable and active competitive force in competition with the Parties and other competitors. Furthermore, the Proposed Purchaser shall have established capabilities or a track record in the manufacture, marketing and distribution of animal health products in the EEA/UK as well as adequate manufacturing and regulatory capabilities to successfully implement a production transfer in relation to the Divestment Business. Moreover, the Proposed Purchaser shall have sufficient R&D resources and experience to develop the relevant [...] products. Finally, the Proposed Purchaser shall have complementary products and expertise relevant to the Divestment Business.

(a) *Manufacture, Marketing and Distribution of Animal Health Products in the EEA/UK*

- (19) Dechra has eight manufacturing sites, out of which three are located in the EEA/UK. More specifically, the company has manufacturing facilities in the UK, the Netherlands and Croatia.¹¹
- (20) The manufacturing of the Otitis Divestment Business products is [...]. The Trustee considers that based on its manufacturing capabilities, in combination with its supply chain expertise, Dechra is well positioned to oversee the various elements of the manufacture and supply chain of the Otitis Divestment Business in an adequate manner.¹²
- (21) Dechra has established commercial operations across the EEA/UK. More in particular, Dechra has sales organizations in all EEA/UK countries in which the Otitis Divestment Business is currently marketed. Moreover, Dechra has a significant sales force of employees including technical, marketing, support and warehouse functions in the EEA/UK countries where the Otitis Divestment Business has revenues.¹³

⁹ Reasoned Opinion, Section 5.

¹⁰ Reasoned Opinion, Section 5.

¹¹ Reasoned Opinion, Section 5.

¹² Reasoned Opinion, Section 5.

¹³ Reasoned Opinion, Section 5.

(22) Based on the information above and the Trustee’s Reasoned Opinion¹⁴ , the Commission considers that Dechra has the proven experience, manufacturing, marketing and distribution capabilities to maintain and develop the Otitis Divestment Business.

(b) *Manufacturing and Regulatory Capabilities for Implementation of Production Transfer*

(23) The Commitments specify that the Proposed Purchaser shall have adequate manufacturing and regulatory capabilities to successfully implement a production transfer in relation to the Divestment Business (where relevant). In the context of the acquisition of the Otitis Divestment Business, a production transfer will not be performed¹⁵, [...].¹⁶

(24) Dechra has extensive experience of dealing with the regulators responsible for granting marketing authorisations for new products. In the past five years, Dechra has been granted a high number of marketing authorisations for CA products in the EEA/UK, relating to a large number of CA products.¹⁷

(25) Based on the aforementioned considerations, the Trustee concludes that this criterion is not relevant in this particular situation. In view of this, the Commission also concludes that the criterion of having manufacturing capabilities for the implementation of a production transfer is not relevant and that Dechra has the necessary regulatory capabilities to implement the transfer of the relevant marketing authorisations.

(c) *Sufficient R&D Resources and Experience to Develop the Relevant [...] Products*

(26) Dechra invested a significant amount in R&D in 2019. The company had a high number of projects in the product development process as per its 2019 annual report, of which a significant proportion were in the development stage.¹⁸

(27) Based on its assessment of Dechra’s R&D resources and experience, the Trustee considers that the company fulfils this purchaser criterion.¹⁹

(28) On the basis of the Trustee’s Reasoned Opinion²⁰ and all the other information at its disposal, the Commission considers that Dechra has sufficient R&D resources and experience to develop the relevant [...] products.

(d) *Complementary Products and Expertise Relevant to the Divestment Business*

(29) Dechra has a strong companion animal product portfolio, including several products for the treatment of otitis. More in particular, the company has been active in the

¹⁴ Reasoned Opinion, Section 5.

¹⁵ [...].

¹⁶ Reasoned Opinion, Section 5.

¹⁷ Reasoned Proposal in respect of an acquisition of the Otitis Divestment Business by Dechra (“Reasoned Proposal”) of 10 June 2020.

¹⁸ Reasoned Opinion, Section 5.

¹⁹ Reasoned Opinion, Section 5.

²⁰ Reasoned Opinion, Section 5.

otitis market in the EEA/UK since 2008. In fact, Dechra has a number of on-market daily use otitis products in its offering [...] complementing the Otitis Divestment Business.²¹

- (30) Based on the information above and the Trustee's Reasoned Opinion²², the Commission considers that Dechra has sufficient complementary products and expertise relevant to the Otitis Divestment Business.

2.1.2.3. Incentives to maintain and develop the Divestment Business

- (31) The Trustee's Reasoned Opinion concludes that the purchase of the Otitis Divestment Business represents for Dechra an opportunity to consolidate its presence in the otitis markets. Indeed, post-Transaction Dechra will be able to take advantage of the complementary product portfolio and offer a broader range of otitis products. A long acting product, like Osurnia, is a useful addition to Dechra's portfolio of daily use products. Furthermore, the acquisition of the Otitis Divestment Business will contribute to increased shareholders returns.²³

- (32) Based on the information above and the Trustee's Reasoned Opinion and all the other information at its disposal, the Commission considers that Dechra has the incentives to maintain and develop the Otitis Divestment Business.²⁴

2.1.3. Absence of *prima facie* competition concerns

- (33) The acquisition of the Otitis Divestment Business by Dechra is *prima facie* not likely to give rise to competition concerns. Dechra commercializes in the EEA several daily-use otitis products [...]. The Otitis Divestment Business consists of Osurnia [...]. The Commission concluded in the Decision that long-acting and daily-use otitis products constitute distinct product markets.²⁵ On that basis, there is no overlap between the products of Dechra and the Otitis Divestment Business.

- (34) In light of the above, the Commission considers that the acquisition of the Otitis Divestment Business by Dechra is neither likely to create *prima facie* competition concerns, nor to give rise to a risk that the implementation of the Commitments will be delayed.

2.1.4. Conclusion

- (35) In view of the above, the Commission considers that Dechra meets the Purchaser Criteria.

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

- (36) The Commission has reviewed the Transaction Agreements and considers that the Transaction Agreements reflect the Parties' obligations set out in the Commitments.

²¹ Reasoned Opinion, Section 3.

²² Reasoned Opinion, Section 5.

²³ Reasoned Opinion, Section 5.

²⁴ Reasoned Opinion, Section 5.

²⁵ Paragraph 57 of the Decision.

The Trustee observed no deviations between the Commitments and the Transaction Agreements. Moreover, Dechra confirmed that it is satisfied with the manner the Commitments are reflected in the Transaction Documents. Furthermore, Dechra has also confirmed to the Trustee that it does not want to acquire any Personnel which was included at the option of the Purchaser under clause 9 of the Main Commitments.²⁶

- (37) Therefore, the Commission concludes that the Otitis Divestment Business is being sold in a manner consistent with the Commitments including their objective to bring about a lasting structural change in the market.

3. CONCLUSION

- (38) Based on the above assessment, the Commission approves Dechra as a suitable purchaser of the Otitis Divestment Business.
- (39) Based on the Transaction Agreements, the Commission further concludes that the Otitis Divestment Business is being sold in a manner consistent with the Commitments.
- (40) This 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 Commitments.
- (41) This Decision is based on paragraph 22 of the Main Commitments attached to the Decision.

For the Commission

(Signed)
Olivier GUERSENT
Director-General

²⁶ Reasoned Opinion, Section 5.