CMA/15/2021

Anticipated acquisition by AstraZeneca plc of Alexion Pharmaceuticals, Inc.

Decision on relevant merger situation and substantial lessening of competition

ME/6926/21

Please note that [✂] indicates figures or text which have been deleted or replaced in ranges at the request of the parties or third parties for reasons of commercial confidentiality.

SUMMARY

1. AstraZeneca plc (**AstraZeneca**) has agreed to acquire Alexion Pharmaceuticals, Inc. (**Alexion**) (the **Merger**). AstraZeneca and Alexion are together referred to as the **Parties**.

2. The Competition and Markets Authority (**CMA**) believes that it is or may be the case that each of AstraZeneca and Alexion is an enterprise; that these enterprises will cease to be distinct as a result of the Merger; and that the turnover test is met. Accordingly, arrangements are in progress or in contemplation which, if carried into effect, will result in the creation of a relevant merger situation.

3. Both AstraZeneca and Alexion have early-stage pipeline pharmaceutical products which could be developed to treat Peripheral T-cell Lymphoma (**PTCL**), a rare and aggressive form of cancer. An additional pipeline-to-pipeline overlap arises as a result of AstraZeneca's material influence over Dizal Pharmaceutical (**Dizal**), which is also developing a product which could be developed to treat PTCL.

4. Accordingly, the CMA has assessed whether the Merger will result in a realistic prospect of a substantial lessening of competition (**SLC**) as a result of a loss of potential and dynamic competition in relation to the supply of

products for the treatment of PTCL in the UK, with a particular focus on patients for whom first-line treatment has been unsuccessful.

5. Based on the evidence available, the CMA considers the products developed by Alexion and Dizal may closely compete and that therefore, the Merger may have an impact on the Merged Entity's incentives to invest in the continued development of these products. However, the CMA considers there would be a sufficient competitive constraint post-merger in respect of competition on innovation in and marketed supply of treatments for PTCL. Therefore, the CMA believes the Merger does not give rise to a realistic prospect of a SLC as a result of horizontal unilateral effects in relation to PTCL.

6. The CMA also assessed the impact of the Merger in relation to the development of products targeting a key part of the immune system known as the complement system on a global basis, where Alexion appears to have a particularly strong presence. In view of the large number of firms engaged in research and development (**R&D**) in respect of products targeting the complement system, the CMA does not believe there is a realistic prospective of an SLC as a result of horizontal unilateral effects in relation to the complement system.

7. The Merger will therefore **not be referred** under section 33(1) of the Enterprise Act 2002 (the **Act**).

ASSESSMENT

Parties

8. AstraZeneca is a multinational pharmaceutical company headquartered in England.[1] It is listed on the London, Stockholm and Nasdaq stock exchanges. AstraZeneca's business comprises three core therapy areas: oncology; cardiovascular, renal and metabolism; and respiratory and immunology.[2] The Parties submitted that the treatment of rare diseases has not been a focus for AstraZeneca's development pipeline.[3] AstraZeneca has a [✂] shareholding in Dizal. As a result of relevant product overlaps[4], the CMA has considered, as part of its assessment of the Merger, whether AstraZeneca has material influence over Dizal.[5]

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[1] AstraZeneca operates in over 100 countries, with strategic global research and development centres in Cambridge (UK), Gothenburg (Sweden) and Gaithersburg (US). Merger Notice, 24 May 2021, paragraphs 4 and 23.
[2] Merger Notice, 24 May 2021, paragraph 4 and 23.
[3] Merger Notice, 24 May 2021, paragraph 6.
[4] See further paragraph 40.
[5] See further paragraphs 21 to 29.

9. The turnover of AstraZeneca in 2020 was approximately £20.2 billion worldwide and approximately [✂] in the UK.

10. Alexion is a biopharmaceutical company globally headquartered in the United States of America, with an EMEA headquarters in Switzerland.[6] Alexion is listed on Nasdaq.[7] Alexion's product portfolio focuses on 'rare and ultra-rare diseases',[8] ie diseases for which there is high unmet medical need.[9] Alexion has an expertise in the complement system which is a key part of the immune system.[10]

11. The turnover of Alexion in 2020 was approximately £4.3 billion worldwide and approximately [✂] in the UK.

Transaction

12. The Parties entered into a merger agreement on 12 December 2020, pursuant to which AstraZeneca, through three wholly-owned subsidiaries,[11] will acquire Alexion.[12]

13. The Merger will be effected through a US statutory merger in which each shareholder of Alexion will receive (per share) USD 60 in cash and 2.1243 new AstraZeneca American depository shares listed on Nasdaq (at a price of USD 175).[13] The total equity offer consideration for the deal is USD 39.4 billion (approximately £29.6 billion).

14. The Merger was also the subject of review by competition authorities in the United States and EU among others.[14]

Rationale for the Transaction

15. The Parties submitted that R&D for rare diseases is challenging as it is difficult to diagnose patients with rare or ultra-rare diseases.[15] The Parties submitted that, while Alexion has specialist scientific processes for identifying

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[6] Merger Notice, 24 May 2021, paragraph 5.
[7] Merger Notice, 24 May 2021, paragraphs 5 and 26.
[8] See further paragraph 32. For the purposes of this decision, references to 'rare' diseases also include 'ultra-rare' diseases unless otherwise specified.
[9] Alexion markets five therapies to treat seven diseases (most of which are rare diseases), and most of its assets relate to rare diseases. Merger Notice, 24 May 2021, paragraph 5.
[10] Merger Notice, 24 May 2021, paragraph 25.
[11] Delta Omega Sub Holdings Inc. (BidCo), Delta Omega Sub Holdings Inc. 1 (Merger Sub Inc), and Delta Omega Sub Holdings LLC 2 (Merger Sub LLC).
[12] Merger Notice, 24 May 2021, paragraph 37. Pursuant to the signing of the Merger Agreement, AstraZeneca has announced its intention to acquire Alexion. The registration statement under the US Securities Act of 1933 was published on 19 February 2011. A shareholder circular was published on 12 April 2021.
[13] Merger Notice, 24 May 2021, paragraph 43.
[14] Merger Notice, 24 May 2021, paragraph 69.
[15] Merger Notice, 24 May 2021, paragraph 8.

rare disease patients that can be enrolled in clinical trials and highly specialised sales personnel,[16] AstraZeneca has neither the required R&D processes nor the commercial expertise to develop and market therapies for rare diseases effectively.[17] The Parties submitted that the Merger represents an opportunity for AstraZeneca to expand patient access to treatments for rare diseases by leveraging Alexion's scientific expertise in AstraZeneca's core therapy areas and using AstraZeneca's global footprint. The Parties told the CMA that the Merger would benefit patients by expanding access to life-changing therapies and enhancing R&D and innovation across the combined portfolio.

16. The internal documents assessed by the CMA were consistent with the Parties' submissions on the rationale for the Transaction.

Jurisdiction

17. The initial period for consideration of the Merger under section 34ZA(3) of the Act started on 25 May 2021 and the statutory 40 working day deadline for a decision is therefore 21 July 2021.

AstraZeneca and Alexion

18. Each of the Parties is an enterprise for the purposes of the Act. As a result of the Merger, AstraZeneca will obtain sole control over Alexion and these two enterprises will cease to be distinct for the purposes of section 23(1)(a) of the Act.

19. Alexion's UK turnover exceeds £70 million. Accordingly, the turnover test set out at section 23(1)(b)(i) of the Act is satisfied.

20. The CMA therefore believes that it is or may be the case that, as a result of the Merger, arrangements are in progress or in contemplation which, if carried into effect, will result in the creation of a relevant merger situation.

AstraZeneca's [✂] *material influence*

21. In the light of product overlaps in the treatment of PTCL as between AstraZeneca, Dizal and Alexion,[18] the CMA has assessed whether AstraZeneca has material influence over Dizal. Dizal is an enterprise for the purposes of the Act.

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[16] Merger Notice, 24 May 2021, paragraph 8.
[17] Merger Notice, 24 May 2021, paragraph 8.
[18] See further paragraph 3.

22. In assessing whether material influence exists, the CMA focused on AstraZeneca's ability to materially influence policy relevant to the behaviour of Dizal in the marketplace.[19] The policy of Dizal in this context means the management of its business, including the strategic direction and its ability to define and achieve its commercial objectives.[20] The assessment of material influence requires a case-by-case analysis and the CMA will have regard to all the circumstances of the case.[21] The CMA may take into account a number of factors in assessing whether material influence exists, including the level of shareholdings, board representation and other supporting factors.[22]

23. As set out in Table 1 below, AstraZeneca is the [✂] in Dizal.[23]

Table 1: [✂]

24. AstraZeneca has appointed two of the seven existing directors of Dizal, both of whom are senior AstraZeneca employees with significant pharmaceutical industry expertise.[24]

25. The Parties submitted that an IPO is envisaged in respect of Dizal.[25] The registration of the listing with the Shanghai Stock Exchange (***SSE***) commenced in March 2021 and it remains subject to further regulatory approval by the China Securities Regulatory Commission (**CSRC**).[26]

26. The Parties submitted that AstraZeneca has material influence over Dizal within the meaning of the Act and that this remains unchanged despite the ongoing IPO process.[27] This is on the basis of its approximately [✂] shareholding and its board representation,[28] neither of which have changed as a result of registration of the listing.[29]

27. The CMA believes that AstraZeneca has the ability to exercise material influence over Dizal as a result of a combination of mutually reinforcing factors, namely:

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[19] CMA2, paragraph 4.21.
[20] CMA2, paragraph 4.21.
[21] CMA2, paragraph 4.22.
[22] CMA2, paragraph 4.23 to 4.24.
[23] Merger Notice, 24 May 2021, paragraph 450.
[24] Mr Menelas Pangalos (Executive Vice-President, Research & Development BioPharmaceuticals, AZ) and Mr Rodolphe Grépinet (Vice President, Corporate Development, AZ). Dizal's Board of Directors can be viewed on its website: Board of Directors.
[25] Merger Notice, 24 May 2021, paragraphs 456 to 459.
[26] Merger Notice, 24 May 2021, paragraphs 456 to 457.
[27] Merger Notice, 24 May 2021, paragraphs 455 and 461. While the IPO process is ongoing and subject to regulatory approval. [✂].
[28] [✂].
[29] Merger Notice, 24 May 2021, paragraphs 460 to 461. [✂].

(a) [✂].[30] The CMA considers that the scale of AstraZeneca's shareholding will, in practice, allow it to influence Dizal's management, and, therefore, Dizal's policy in the marketplace (including by potentially blocking special resolutions).

(b) AstraZeneca has appointed two of the seven current directors of Dizal (both of whom are senior AstraZeneca employees with significant pharmaceutical industry expertise). [✂].[31] [✂].[32] The CMA considers that material influence over Dizal is indicated by the ability of the AstraZeneca appointed directors [✂].

(c) The CMA considers that AstraZeneca's significant pharmaceutical industry expertise can be expected to lead to its advice being followed to a greater extent than otherwise would be the case.

28. In light of the above, AstraZeneca and Dizal have ceased to be distinct enterprises for the purposes of the Act. Accordingly, the CMA has taken Dizal's product portfolio into account as part of its competitive assessment.

Counterfactual

29. The CMA assesses a merger's impact relative to the situation that would prevail absent the merger (ie the counterfactual).[33] The counterfactual may consist of the prevailing conditions of competition, or conditions of competition that involve stronger or weaker competition between the merger firms than under the prevailing conditions of competition.[34] In determining the appropriate counterfactual, the CMA will generally focus only on potential changes to the prevailing conditions of competition where there are reasons to believe that those changes would make a material difference to its competitive assessment.[35]

30. In this case, the CMA has found no evidence supporting a different counterfactual, and neither the Parties nor third parties have put forward arguments to support a different counterfactual. Therefore, the CMA believes the prevailing conditions of competition to be the relevant counterfactual.

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[30] [✂].
[31] [✂].
[32] [✂].
[33] Merger Assessment Guidelines (CMA129), 18 March 2021 (**Merger Assessment Guidelines**), paragraph 3.1.
[34] Merger Assessment Guidelines, paragraph 3.2.
[35] Merger Assessment Guidelines, 18 March 2021, paragraph 3.9.

Background

31. The CMA's assessment concerns pharmaceutical products that are still in development, ie pipeline drugs.[36] More specifically, the Parties' activities overlap in relation to the development of treatments for certain rare diseases.

32. The UK Rare Diseases Framework defines a rare disease as one that affects less than 1 in 2,000 people.[37] Rare diseases can be both life-limiting and life-threatening or chronically debilitating conditions. The Parties told the CMA that there are not yet satisfactory defined protocols for diagnosis, prevention and treatment of these diseases.[38]

33. By way of background to the analysis set out in this Decision, this section provides a brief overview of:

    (a) the structure of supply in the pharmaceutical sector (including the key stages of the supply cycle);

    (b) PTCL (including an overview of the Parties' activities and the competitive landscape more generally); and

    (c) the complement system (including an overview of the Parties' activities and the competitive landscape more generally).

Supply in the pharmaceutical sector

34. At a high level, the development of pharmaceutical products can be divided into three broad stages: (i) early R&D; (ii) clinical development, comprised of sequential phases of clinical trials known as Phases I, II and III; and (iii) the obtaining of regulatory approvals. It may take several years to develop a new treatment from the earliest stages of discovery to the time it is available for treating patients:

    (a) Early R&D: the initial stages of discovery will generally involve researchers identifying target compounds and testing them for factors such as safety, efficacy and dosage to ensure these compounds are suitable for human testing in clinical trials. The Parties submitted that a relatively small percentage of drugs and biologics proceed past this stage.

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[36] The Merger does not result in any marketed-to-marketed product overlaps between AstraZeneca and Alexion.
[37] The UK Rare Diseases Framework (published 9 January 2021). The Parties submitted that while there is no official definition of an 'ultra-rare' disease, the industry typically considers an ultra-rare disease to be one that affects fewer than 1 in 50,000 people. Merger Notice, 24 May 2021, paragraph 166.
[38] Merger Notice, 24 May 2021, paragraph 26.

Pharmaceutical companies tend to explore a number of pre-clinical products before deciding which ones to pursue at a clinical trial stage.[39]

(b) Phase I: during this phase, new products are tested to determine the safety of single doses in a small number of healthy volunteers.[40] The Parties submitted that Phase I trials typically last approximately [✂] (as an industry-wide median duration).[41]

(c) Phase II: if the treatment proves to be safe at Phase I, a Phase II study would be undertaken to determine the effectiveness of the drug in people with the condition to be treated.[42] The Parties submitted that Phase II studies typically last approximately [✂] (as an industry-wide median duration) and involve larger numbers of people.[43]

(d) Phase III: if a drug shows effectiveness in Phase II, a larger Phase III study is conducted. These clinical trials take place at different locations (multi-centre) and across several countries and typically last around [✂] (as an industry-wide median duration).[44]

(e) It is widely recognised that the success of products in clinical trials is a particularly important determinant of whether these products are authorised for eventual commercialisation.[45] The amount and quality of clinical data obtained from trials are key factors in product development, with clinical trials accounting for a significant proportion of the investment needed to develop a new product.

(f) Obtaining of regulatory approvals: after the clinical trial stage, a product would enter the registration phase where data from all three phases is presented to the regulatory authorities.[46] Once licensed, the National Institute for Health and Care Excellence (**NICE**), for England and Wales, and the Scottish Medicines Consortium (**SMC**), for Scotland, would appraise the product and look at issues such as cost effectiveness.[47] If NICE or the SMC recommends the drug for use through the NHS, then it

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[39] Merger Notice, 24 May 2021, paragraph 148.
[40] Merger Notice, 24 May 2021, paragraph 148.
[41] Merger Notice, 24 May 2021, paragraph 148.
[42] Merger Notice, 24 May 2021, paragraph 149. Certain treatments may also exceptionally move directly from pre-clinical trials to Phase II clinical trials if adequate data (eg in relation to safety) has been determined through other related trials.
[43] Merger Notice, 24 May 2021, paragraph 149.
[44] See Response to CMA RFI 1, dated 8 April 2021, paragraph 77.
[45] ME/6831/19 *Anticipated acquisition by Roche Holdings, Inc. of Spark Therapeutics, Inc,* 16 December 2019, paragraph 28.
[46] In the UK, licences are granted by The Medicines and Healthcare Products Regulatory Agency (**MHRA**) and, pre-Brexit, The European Medicines Agency (**EMA**). Response to CMA RFI 1, dated 8 April 2021, paragraph 80. Note that MHRA approval can in principle be obtained by relying on data from trials run outside of the UK, provided the trial met UK standards.
[47] For further detail see Response to CMA RFI 1 dated 8 April 2021, paragraphs 75 to 85.

can be made available to patients through the NHS.[48] In order for medicines to be made available to UK patients through the NHS, it is also necessary to gain market access and reimbursement after licencing.[49]

35. The CMA refers to 'supply' and 'treatment' in this decision to describe both the development (ie R&D/pipeline activities) and the ultimate end-supply of pharmaceutical products, unless otherwise specified.

PTCL

36. PTCL is a rare and aggressive form of cancer that is difficult to cure.[50] It is a sub-type of Non-Hodgkin Lymphoma (**NHL**) that affects the T-cells.[51] There is a number of sub-types of PTCL and a heterogeneous 'not-otherwise-classified' sub-group.[52] Treatments for PTCL must be prescribed.[53] PTCL is typically treated with a combination of drugs including chemotherapy, steroids and stem cell treatments, although a distinction is drawn between the first-line and relapse/refractory setting.[54] Specifically, PTCL can be treated by inhibiting particular protein kinases.[55]

37. The Parties overlap in respect of certain pipeline pharmaceutical products, including for the treatment of relapse/refractory PTCL.[56] The term 'relapsed' refers to a disease that reappears or grows again after a period of remission.

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[48] Response to CMA RFI 1, dated 8 April 2021, paragraph 157. For completeness, depending on the therapy area and the healthcare organisation in which the products are prescribed, there may be other processes that must be completed in order for a treatment to be prescribed locally.
[49] Response to CMA RFI 1, dated 8 April 2021, paragraph 83.
[50] Approximately 80% of patients relapse after first-line treatment, and the disease has a median time to death from diagnosis of approximately three years. The second- and third-line treatments of PTCL may involve drugs that inhibit particular dysregulated biochemical reactions in patients to prevent the growth of the cancer. Merger Notice, 24 May 2021, paragraph 441.
[51] Merger Notice, 24 May 2021, paragraph 441. PTCL accounts for approximately 14% of cases of NHL.
[52] See Swerdlow, S. H., Campo, E., Pileri, S. A., Harris, N. L., Stein, H., Siebert, R., Advani, R., Ghielmini, M., Salles, G. A., Zelenetz, A. D., & Jaffe, E. S. (2016). The 2016 revision of the World Health Organization classification of lymphoid neoplasms | Blood | American Society of Hematology, 127(20), 2375–2390.
[53] Response to CMA RFI 1, dated 8 April 2021, paragraph 90.
The prescribing party must be a qualified and authorised health care practitioner, and is likely to be a prescribing health care professional in a hospital trust. Doctors decide which prescription medicines and medical devices the patient takes or uses and can make recommendations for over-the-counter medicines. If there is more than one licensed and reimbursed product available for a particular disease, patient choice will be a consideration. Merger Notice, 24 May 2021, paragraphs 163 to 165.
[54] Merger Notice, 24 May 2021, paragraph 446.
[55] Merger Notice, 24 May 2021, paragraph 446.
[56] For completeness, the Parties' activities also overlap in the development of treatments for lupus nepthritis (**LN**) and follicular lymphoma (**FL**). In view of the large number of available pipeline and marketed products and the absence of concerns expressed by third parties, the CMA does not believe there is a realistic prospect of an SLC as a result of horizontal unliateral effects in relation to either of these overlaps. Accordingly, they are not considered further in this Decision.
Furthermore, the CMA also considered an input foreclosure theory of harm [✂]. However, on the basis of the evidence available, the CMA believes that AstraZeneca would lack the ability to foreclose. Accordingly, this is not considered further in this Decision.

The term ‘refractory’ is used to describe when the cancer does not respond to, or resists, the treatment.

38. Treatment guidelines generally recommend the inclusion of relapsed/refractory patients in clinical trials, there being no recommended course of treatment currently.[57]

39. As outlined in Table 2 below, the Merger involves three products for the treatment of relapse/refractory PTCL developed by the Parties.[58] All three of these products are pipeline products in Phase I or Phase II clinical trials.

Table 2: [✂]

40. The Parties’ pipeline assets currently in development for relapse/refractory PTCL have the mode of action (**MoA**) of inhibiting one or multiple sub-types of protein kinases:[59]

(a) AstraZeneca’s [✂] inhibitor, which is being developed to inhibit the specific protein kinase [✂].

(b) Dizal’s DZD4205 is being developed to inhibit the activity of the Janus kinases (**JAK**) family of proteins, and in particular JAK1 and JAK3 pathways, so as to inhibit the oncological effects of the dysregulation of the pathways caused by mutated JAK proteins.

(c) Alexion’s cerdulatinib is being developed as a dual spleen tyrosine kinase (**SYK**)/JAK inhibitor, and inhibits the activity of SYK, JAK1, JAK3 and tyrosine kinase 2 (**TYK2**).[60]

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[57] Merger Notice, 24 May 2021, paragraphs 478 to 481.
For completeness, NICE has published guidance on the treatment of NHL which includes guidance on the treatment of PTCL. The approaches outlined are broadly consistent with those set out in the European Society for Medical Oncology (**ESMO**) guidelines. The NICE guidelines recommend the use of CHOP (cyclophosphamice, hydroxydaunorubicin, vincristine and prednisole) chemotherapy followed by autologous stem stell transplantation for first-line treatment of PTCL. It is however, silent on the recommended course of treatment for relapse/refractory PTCL patients whereas the ESMO guidelines explain ‘including into clinical trials is highly encouraged’ for these patients.
NICE guidelines are available here: Non-Hodgkin’s lymphoma: diagnosis and management (nice.org.uk)
ESMO guidelines are available here: Peripheral T-cell lymphomas: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up† - Annals of Oncology.
[58] See also sections ‘Parties’ and, as regards the relevance of Dizal, ‘Jurisdiction’ above.
[59] Merger Notice, 24 May 2021, paragraph 448(a)-(c).
[60] The Parties’ submitted that [✂]. See Merger Notice, 24 May 2021 [✂]. However, the evidence in the Parties’ internal documents in this regard was ultimately mixed. For this reason, the CMA has proceeded on the basis that [✂].

41. As set out in the Competitive Assessment below, there are two already-marketed products available in the UK[61] and several pipeline treatments.

Complement system

42. The complement system is a key part of the immune system.[62] It is made up of a large number of distinct plasma proteins that, when triggered, react with one another to induce a series of inflammatory responses through different cascades of biochemical reactions (or 'pathways') leading to clearance of foreign and damaged cells from the body. Therapeutic efforts targeting the complement system revolve around the inhibition of one or more of such pathways.[63]

43. Alexion has a particular expertise in biological research into the complement system.[64] However, the Parties submitted that Alexion's complement system technology platform has implications for the treatment of a wide variety of other diseases, beyond Alexion's rare disease focus.[65] While AstraZeneca does not have any marketed or clinical pipeline products that target the complement system, [✂].[66]

44. The evidence available to the CMA indicates that there are at least 25 competitors with R&D programmes targeting the complement system worldwide.[67] However, the evidence also suggests that Alexion is the only supplier that currently markets products targeting the complement system.[68]

Frame of reference

45. The assessment of the relevant market is an analytical tool that forms part of the analysis of the competitive effects of the merger and should not be viewed as a separate exercise.[69]

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[61] For completeness, in the US, the local authorities have (conditionally) approved four other products for relapse and refractory patients: pralatrexate; romidespin; brentuximab; belinostat. These products are not available in the UK. See for example, Document [✂], submitted by AstraZeneca in response to the CMA's s109 Notice on 28 April (**s109**) [✂].
[62] Merger Notice, 24 May 2021, paragraph 206.
[63] See P. N., Spiller, B., & Chavez, R. The complement system: History, pathways, cascade and inhibitors in: European Journal of Microbiology and Immunology Volume 2 Issue 2 (2012), 2(2), 103–111,
[64] Alexion's website states: 'Our legacy in rare disease is rooted in being the first to translate the complex biology of the complement system into transformative medicines.' Research and Development | Alexion
[65] Merger Notice, 24 May 2021, paragraph 66.
[66] Merger Notice, 24 May 2021, paragraph 210. [✂].
[67] Response to [✂], 19 March 2021, paragraphs 43 to 44 and response to [✂], 9 April 2021, paragraphs 43 to 44.
[68] The CMA understands that Alexion currently markets or develops [✂] products [✂].
[69] Merger Assessment Guidelines, from paragraph 9.1.

46. Market definition involves identifying the most significant competitive alternatives available to customers of the merger firms.[70] In some cases market definition can be an important part of the competitive assessment process. In other cases, the evidence gathered as part of the competitive assessment, which will assess the potentially significant constraints on the merger firms' behaviour, will capture the competitive dynamics more fully than formal market definition.[71] There may be no need for the CMA's assessment of competitive effects to be based on a highly specific description of any particular market (including, for example, descriptions of the precise boundaries of the relevant markets and bright-line determinations of whether particular products or services fall within it).[72] The CMA may take a simple approach to defining the market – for example, by describing the market as comprising the most important constraints on the merger firms that have been identified in the CMA's assessment of competitive effects.[73] The approach taken by the CMA will reflect the circumstances of the case.

Product scope

PTCL

47. As set out above, the Parties' activities overlap in the treatment of relapse/refractory PTCL, a sub-category of PTCL patients for whom first-line treatment is unsuccessful.

48. The Parties submitted that the product scope of the frame of reference should include all treatments for relapsed/refractory PTCL.[74] The Parties submitted that, while PTCL treatments can be distinguished based on the patient population for which the treatment is targeted (ie first-line or relapse/refractory), all the therapy types for relapse/refractory patients constrain each other. The Parties submitted that the high rate of patient relapse/refraction in PTCL means that physicians will typically cycle through the available treatments with different MoAs (which are seen as interchangeable due to the lack of so-called biomarker testing available in a clinical setting).[75]

49. The CMA agrees that it is appropriate to draw a distinction between the first-line and relapse/refractory treatment settings given the distinction drawn in

[70] Merger Assessment Guidelines, paragraph 9.2.
[71] Merger Assessment Guidelines, paragraph 9.2.
[72] Merger Assessment Guidelines, paragraphs 9.1 to 9.5.
[73] Merger Assessment Guidelines, paragraph 9.5.
[74] Merger Notice, 24 May 2021, paragraph 523.
[75] Merger Notice, 24 May 2021, paragraphs 498 to 523.

treatment guidelines.[76] In addition, clinicians confirmed that the majority of PTCL patients will either fail treatment or their disease will relapse and that ultimately, for these patients, there is no standard treatment.[77] For this reason, relapse/refractory PTCL patients have a specific set of needs and there are a range of investigational drugs being explored specifically in respect of relapse/refractory PTCL.[78]

50. Furthermore, the evidence available supports the Parties' submissions that it is not necessary to segment the market by PTCL subtype when assessing competition between pipeline products. The Parties' internal documents indicated that treatments are not typically developed for specific PTCL subtypes.[79]

51. The CMA has not previously assessed overlaps between Phase I or Phase -II pipeline or marketed products for the treatment of PTCL or other oncology conditions. However, in previous decisions, the CMA has assessed marketed products alongside pipeline products whilst taking into consideration differences in the advancement of their development.[80] Further, in recent decisional practice, the CMA has defined relevant product markets based on the ultimate aim or intended use of the treatment (eg the intended therapeutic indication).[81]

52. Accordingly, in line with its previous decisional practice and consistent with the available evidence in this case, the CMA has taken product indications and the locus of the Parties' overlapping activities as its starting point in the analysis and assessed the supply of products for the treatment of relapse/refractory PTCL patients without further segmentation.[82]

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[76] As noted above, treatment guidelines generally recommend the inclusion of patients in clinical trials in the relapsed/refractory setting, there being no recommended course of treatment currently. See paragraph 38 and footnote 57.
[77] For example, note of call with [✂], 29 April 2021, paragraph 9 and note of call with [✂], 5 May 2021, paragraph 8.
[78] Furthermore, one clinician also advised that in general, trials and approvals for relapse/refractory PTCL are conducted separately to that of first-line PTCL treatments, in order to assess the safety and relapse setting before introducing it into the frontline setting. Note of call with [✂], 29 April 2021, paragraph 14.
[79] For example, document titled [✂], provided by AstraZeneca in response to the s109. Furthermore, in respect of DZD4205, initial trial results have indicated a response rate across all tested PTCL subtypes. For completeness, initial results indicate [✂]. Merger Notice, 24 May 2021, paragraph 519.
[80] See for example, *Anticipated acquisition by Roche Holdings, Inc. of Spark Therapeutics, Inc (ME/6831/19)*, 16 December 2019.
[81] *Anticipated acquisition by Roche Holdings, Inc. of Spark Therapeutics, Inc (ME/6831/19*), 16 December 2019, paragraphs 129 to 144.
[82] The Parties submitted that due to the early stage of development of the Parties' products, they were not able to provide ATC codes which have been used in precedents to define product frames of reference. The CMA notes that for some of the Parties' products, internal documents suggest that different indications are pursued for a product – starting with a larger number in early stages which is narrowed down over the course of the different phases in its development. The CMA further notes that for the products for which the Parties were able to provide ATC codes, there is no overlap on either ATC levels 3 or 4.

53. The CMA has considered in the competitive assessment the extent to which certain features of the products, such as the MoA, are relevant for the closeness of competition between products.[83]

Complement system

54. The Parties' activities also overlap in relation to their R&D activities in respect of the complement system.[84]

55. While the CMA's assessment of dynamic competition may, in some cases, focus on entry and expansion in relation to specific products, in others, it may consider a broader pattern of dynamic competition in which the specific overlaps may not be identified easily at the point in time of the CMA's assessment.[85] Where this is the case, the CMA may assess a broader loss of competition arising from a reduction in the merger firms' incentives to continue investing in competing programmes or strategies, rather than focusing on individual future overlaps.[86] Accordingly, the CMA has considered whether the Merger may have an impact on competition on a wider basis in respect of the development of products targeting the complement system, encompassing more than a single indication.

56. The CMA has therefore considered a frame of reference that comprises the development of products targeting the complement system which may ultimately treat a wide range of possible indications.

Geographic scope

PTCL

57. The Parties submitted that the appropriate geographic frame of reference is global in scope.[87] The Parties submitted that, because the relevant pipeline products are in an early stage of clinical trials, any commercialisation considerations of the products are carried out at a global level and that the

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[83] For completeness, the CMA considered whether the product frame of reference should be segmented by sub-type or MoA. The CMA notes that if the market were to be segmented on the basis of MoA, the Parties would be active in separate markets noting that DZD4205 and cerdulatinib have similar, but not identical, MoAs. As regards sub-type, generally speaking, the evidence suggests that there is insufficient data on which to draw meaningful conclusions as to the efficacy of those products in development for the treatment of specific PTCL subtypes.
[84] As mentioned above, while AstraZeneca does not have any marketed or clinical pipeline products that target the complement pathway [✂].
Merger Notice, 24 May 2021, paragraphs 210 and 607. Also see paragraph 46 above.
[85] Merger Assessment Guidelines, paragraph 5.20
[86] Merger Assessment Guidelines, paragraph 5.20.
[87] Merger Notice, 24 May 2021, paragraphs 524 to 536.

products developed as a result of these R&D efforts once marketed will not vary between different jurisdictions.

58. The CMA acknowledges that certain competitive parameters relevant to pipeline treatments, such as product quality and innovation, are likely to be set on a global basis.[88] Global competitive conditions will influence the overall timing of entry, and manufacturers' decisions to market products in specific jurisdictions (and which jurisdictions to enter first) will be influenced by the size of that market, the local competitive conditions in each jurisdiction and the incremental cost of entry in a particular jurisdiction. The Parties' internal documents indicate that firms undertake detailed evaluations of different countries to inform launch priorities.[89]

59. However, when a product is ultimately marketed, suppliers primarily compete on price.[90] Local competitive conditions in each relevant jurisdiction will influence competition on price and investment in sales and marketing activities.

60. Accordingly, in line with previous decisional practice, the CMA considers that the relevant geographic frame of reference for the treatment of relapse/refractory PTCL should be national in scope on the basis of national regulatory schemes for authorising and reimbursing treatments, prescribing practices, pricing policies and marketing strategies used by pharmaceutical firms which differ across jurisdictions.[91] However, given that several PTCL products are currently in development and expected to enter the market in the foreseeable future, the CMA has taken a forward-looking approach and has not limited its assessment to currently-marketed products.

61. The CMA has therefore considered the impact of the Merger on the treatment of relapse/refractory PTCL in the UK, whilst taking into account in its competitive assessment the constraint of products in development globally which may not be aimed at marketisation in the UK

Complement system

62. As set out above, the CMA acknowledges that certain competitive parameters, including R&D and innovation, are likely to be set on a global

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[88] See, for *example Anticipated Acquisition of Actavis UK Limited/Auden Mckenzie Holdings Ltd*, (ME/6513/15) 21 May 2015.
[89] For example, AstraZeneca's internal documents indicate that it assessed potential launch opportunities in [✂] more generally (and in this assessment it considered competitors active on a global basis). [✂] submitted by AstraZeneca in response to the s109.
[90] Pricing is important in jurisdictions such as the UK, which is characterised by a single buyer (the NHS), tender frameworks and budget constraints.
[91] *Anticipated acquisition by Roche Holdings, Inc. of Spark Therapeutics, Inc (*ME/6831/19*)*, 16 December 2019

basis.[92] Accordingly, the CMA considers the geographic frame of reference as regards the development of products targeting the complement system (and potentially encompassing more than a single indication) may be wider than national.

63. Accordingly the CMA has considered the impact of the Merger on the development of products targeting the complement system on a global basis.

Conclusion on frame of reference

64. For the reasons set out above, the CMA has considered the impact of the Merger in the following frames of reference:[93]

- the supply of products for the treatment of relapse/refractory PTCL in the UK (referred to as the **treatment of PTCL**); and
- the development of products targeting the complement system globally (referred to as **complement therapeutics**).

65. Notwithstanding the above assessment, the CMA has left open the exact frame of reference since, as set out below, the CMA considers the Merger does not give rise to a realistic prospect of an SLC on any frame of reference.

Competitive assessment

Horizontal unilateral effects

66. Unilateral effects can arise in a horizontal merger when one firm merges with a competitor that previously provided a competitive constraint, allowing the merged firm profitably to raise prices or to degrade non-price aspects of its competitive offering (such as quality, range, service and innovation) on its own and without needing to coordinate with its rivals. Horizontal unilateral effects are more likely when the merging parties are close competitors.[94]

67. Unilateral effects may also arise from the elimination of dynamic competition (or innovation competition).[95] A merger may reduce the incentives of dynamic competitors to continue with efforts to enter or expand.[96] Losses of dynamic

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[92] *Anticipated Acquisition of Actavis UK Limited/Auden Mckenzie Holdings Ltd*, (ME/6513/15) 21 May 2015, paragraph 55. Also see *Completed acquisition by Tiancheng International Investment Limited (part of Creat Group Co., Ltd.) of Biotest AG* (ME/6711/17) 15 May 2018.
[93] As mentioned, the CMA refers to 'supply' to describe both the development (i.e. R&D activities), and ultimate end-supply, of PTCL treatments.
[94] Merger Assessment Guidelines, paragraph 4.8.
[95] Merger Assessment Guidelines, paragraph 5.1.
[96] Merger Assessment Guidelines, paragraph 5.3.

competition are more relevant when the investments involved in entering or expanding represent an important part of the competitive process, in industries where the process of entering markets takes place over a long period of time and involves significant costs or risks, or where key aspects of the competitive offering are set during the investment phase rather than flexed on an ongoing basis. One example is pharmaceutical mergers, where investments in new products might involve years of investment in products that may never come to fruition.[97]

68. The CMA assessed whether it is or may be the case that the Merger has resulted, or may be expected to result, in an SLC in relation to horizontal unilateral effects in relation to the treatment of PTCL and complement therapeutics.[98]

Horizontal unilateral effects in the treatment of PTCL

69. The CMA has assessed whether the Merged Entity would have an incentive to abandon or reduce R&D efforts in respect of one or more of its PTCL pipeline products, giving rise to a realistic prospect of an SLC in the treatment of PTCL.[99]

70. Where investment and innovation efforts represent an important part of the competitive process, this can lead to dynamic competitive interactions between potential entrants that are making efforts to enter or expand.[100] Dynamic competitors make these investments in order to win new sales in the future, including by winning sales from other suppliers. A merger involving a dynamic competitor making efforts towards entry or expansion may lead the merged entity to reduce those efforts.[101] After a merger, any profits that the dynamic competitor would expect to 'steal' from the other merger firm would no longer contribute to an incentive to enter, as these profits would already be captured by the merged entity.[102]

71. It is more likely to be profitable for the Merged Entity to abandon or reduce R&D efforts when the products in question are expected to be close alternatives, when there are relatively few existing or pipeline alternatives, and when the business case for making the investments was already marginal. Such abandonment may lead to competition concerns where there is

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[97] Merger Assessment Guidelines, paragraph 5.4.
[98] See also footnote 56.
[99] Merger Assessment Guidelines, paragraph 5.19 (b).
[100] Merger Assessment Guidelines, paragraph 5.18.
[101] Merger Assessment Guidelines, paragraph 5.19(a).
[102] Merger Assessment Guidelines, paragraph 5.19(b).

insufficient dynamic competition, or competition in R&D efforts remaining post-merger, having regard to the particular circumstances of the case.

72. The Parties develop products that pursue a similar (although not identical) MoA, with the alternative pipeline products each pursuing different MoAs. Alexion's cerdulatinib is a dual SYK/JAK inhibitor. Dizal's DZD4205 is a selective JAK1 and JAK3 inhibitor. By contrast, AstraZeneca's product, [✂]. On the basis of evidence from third parties, and in the particular circumstances of the case, the CMA's competitive assessment focused on the two products with a JAK inhibitor MoA: Dizal's DZD4205 and Alexion's cerdulatinib.

73. In assessing horizontal unilateral effects in relation to the treatment of PTCL, the CMA considered:

(a) closeness of competition between the Parties; and

(b) competitive constraints from alternative suppliers.

74. Given the importance of R&D and innovation in this frame of reference, the unfolding nature of the competitive conditions created by such R&D efforts, and the expected launch of treatments, the CMA has placed particular weight on the most recent and forward-looking evidence.

Closeness of competition between the Parties

75. In examining closeness of competition the CMA has considered:

(a) the Parties' submissions;

(b) internal documents of the Parties; and

(c) third party views on closeness of competition.

76. The CMA considered evidence both in relation to the potential closeness of the Parties' specific products (Alexion's cerdulatinib and Dizal's DZD4205) and more generally on the question of whether two PTCL pipeline products with the same and/or similar MoAs would be close competitors.[103]

Parties' submissions

77. The Parties submitted that they are not close competitors within PTCL on the basis that no biomarker testing is available in a clinical setting. The Parties

[103] See also footnote 60.

submitted that physicians are not able to determine in advance whether a particular MoA will be more effective than others in the treatment of PTCL and that, accordingly, clinicians must try different treatments until they find one that works for a particular patient. The Parties also submitted that, given the high rate of relapse, such treatments may only work for a certain period of time, following which the physician will need to try different treatment options with different MoAs. The Parties submitted, therefore, that all marketed and pipeline therapies are within the 'toolbox' of the prescriber, regardless of MoA.[104]

78. The Parties further submitted that, while cerdulatinib and DZD4205 both target the JAK pathway, they are distinct products with different MoAs, efficacy and safety profiles. In particular, the Parties submitted that DZD4205 is a selective JAK inhibitor targeting the JAK1 and JAK3 pathways, which would be suited for the treatment of lymphomas where the JAK pathway is playing a role in the survival and growth of cancerous cells. Conversely, the Parties submitted that Alexion's cerdulatinib is a dual SYK/JAK inhibitor which targets the SYK, JAK1, JAK3 and TYK2 pathways and would be more effective where both the SYK and JAK pathways contribute to the survival of cancerous cells.[105]

Evidence from Internal documents

79. The Parties' internal documents indicate that the Parties consider the competitive landscape for the treatment of PTCL, and the prospects of their own pipeline products, by reference to (inter alia) MoA. For example, a number of internal documents referred to the specific MoA, its overall attributes, and its differentiation from other pipeline products deploying a different MoA.[106]

80. However, the Parties' internal documents also suggest that MoA is only one of a number of factors that the Parties take into account when assessing competitive conditions, and that other important factors include efficacy,

[104] Merger Notice, 24 May 2021, paragraphs 478 and 486.
[105] Merger Notice, 24 May 2021, paragraphs 478 and 492.
[106] An Alexion presentation under the heading [✂] describes cerdulatinib as [✂]. Document titled [✂]. An AstraZeneca internal document [✂], discussing the opportunity for [✂] states that there are [✂]. Document titled [✂] submitted by AstraZeneca in response to the CMA's s109 [✂]. An analyst report prepared for AstraZeneca on Alexion's pipeline products, states that [✂]. Document titled [✂] submitted by AstraZeneca in response to the CMA's s109 [✂].

safety (and patient experience more broadly) and time to market.[107] For example:

(a) An Alexion presentation dated [✂] assesses cerdulatinib and competitors' marketed and pipeline products for PTCL by reference to [✂].[108]

(b) An analyst report [✂], prepared for AstraZeneca on Alexion's pipeline products, notes the [✂].[109]

81. The CMA has not seen any internal documents in which one of the Parties identifies the other as a particularly close competitor. For instance, an Alexion presentation [✂] evaluates Dizal's DZD4205 as one of 12 competing pipeline products to Cerdulatinib.[110] Similarly, an Alexion presentation [✂] which assesses the competitive landscape for PTCL, compares Cerdulatinib to four other marketed or pipeline products, but does not include Dizal's DZD4205.[111]

Third-party evidence

82. The CMA sought evidence from clinicians and the Parties' competitors about the parameters of competition, and closeness of competition between the Parties, including the significance of MoA in determining closeness.

83. While noting a degree of uncertainty in this field, evidence from clinicians indicated that, in the absence of clinical trial data, two treatments with the same or similar MoA – such as Alexion's cerdulatinib and Dizal's DZD420 – are more likely to be considered close alternatives, but if that one proved unsuccessful the prescriber is less likely to turn to the product with the same MoA.[112] [113] [114]

84. This view was generally supported by evidence from the Parties' competitors. For example, one competitor told the CMA that 'after failure of a previous therapy, the general paradigm is to switch mode of action and therapeutic

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[107] See for example [✂] to Alexion's response to the CMA's section 109 28 April 2021, which includes a competitive assessment prepared by Alexion [✂].
More generally, AstraZeneca's internal documents indicate that it assesses whether particular products are first or second line treatments, the overall response rate or 'ORR' and the anticipated timing (among other factors) in its assessment of the competitive landscape. See for example, document titled [✂], submitted by AstraZeneca in response to the s109, [✂].
[108] Document titled [✂] submitted by Alexion in response to the CMA's s109, [✂].
109 Document titled [✂] submitted by AstraZeneca in response to the CMA's s109, [%]
[110] Document titled [✂] submitted by Alexion in response to the CMA's s109, [✂].
[111] Document titled [✂] submitted by Alexion in response to the CMA's s109. The CMA notes that this document post-dates the announcement of the Merger, but is consistent with the other (pre-announcement) evidence set out above.
[112] Note of call with [✂], 29 April 2021, paragraph 20. By way of further example, another clinician told the CMA that, in general, drugs with the same MoA/molecular target can be used interchangeably and frequently only show minor differences in efficacy and toxicity. Response to CMA questionnaire by [✂], paragraph 6.
[113] Note of call with [✂], 5 May 2021, paragraph 43.
[114] Note of call with [✂], 19 April 2021, paragraph 24.

target. A similar mode of action makes two therapeutic options more likely to be alternatives for one another.'[115] Similarly, another supplier told the CMA that 'mode of action is the most direct comparison between products' and that it expected cerdulatinib and DZD4205 to be 'extremely close competitors as the mode of action is the same and they are targeting the same cells and pathway.'[116]

85. Furthermore, the majority of competitors and clinicians that responded to the CMA's investigation considered that suppliers with two candidate products for the treatment of the same indication and the same MoA would be less likely to bring both products to market, although some also noted that the broader commercial context would play a role in the overall decision.[117]

86. However, evidence from clinicians also indicated that there could potentially be a meaningful difference between Dizal's selective inhibitor and Alexion's combined inhibitor. In particular, clinicians told the CMA that Alexion's cerdulatinib would be more likely to have higher efficacy and lower tolerability; and that Dizal's DZD4205 would be more likely to have lower efficacy and higher tolerability. For example, one clinician said: 'as a general rule, you are more likely to see efficacy by targeting more than one target so [Alexion's] JAK/SYK combination would be more likely to give you efficacy. Hitting more than one target is generally better but would also entail more side effects and toxicities.'[118]

87. Moreover, clinicians told the CMA that the existence of the same MoA does not *automatically* mean that two PTCL products will be close competitors:[119] efficacy, safety and tolerability are also important factors. Evidence from clinicians indicates that it is too early to reach a definitive conclusion as to

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[115] Response to CMA questionnaire by [✂], paragraph 9.
[116] Response to CMA questionnaire by [✂], paragraph 7.
[117] For example, one clinician said that, in his experience, 'if a firm is developing two treatments with the same MoA, they are more likely than note to "pick a winner" – however the context and broader environment will also impact the decision.' Note of call with [✂], 29 April 2021, paragraphs 39 to 40. For some of the respondents (for instance, [✂], this response was not dependent on the two products having the same mode of action: they considered that suppliers with two candidate products for the treatment of the same indication would not be likely to bring both products to market.
[118] Note of call with [✂], 29 April 2021, paragraph 31.
Another KOL explained that 'although the mechanisms of action of DZD4205 and cerdulatinib overlap to some extent as they are both JAK inhibitors, the two drugs do not target the exact same pathways and DZD4205 is more selective than cerdulatinib. Consequently, at this stage, it is not obvious that these pipeline drugs will have similar efficacy and safety profiles.' Note of call with [✂], 22 April 2021, paragraph 18.
See also Note of call with [✂], 5 May 2021, paragraphs 25 and 41.
[119] For example, one clinician said: 'given the limited available data, it is too early to compare the efficacy and safety profiles of the two drugs. Even though DZD4205 and cerdulatinib have both shown some preliminary promising results, the limited clinical data available at this stage is insufficient to speculate about the prospects of these two drugs and how closely they will compete.' Note of call with [✂], 19 April 2021, paragraphs 22 and 24.

whether Dizal's and Alexion's PTCL products are close competitors since trial data is required to confirm this.[120]

Conclusion on closeness of competition

88. Based on the available evidence, the CMA cannot exclude that Alexion's cerdulatinib and Dizal's DZD4205 are close competitors. In particular, in the absence of clinical data to the contrary, two treatments for the same indication with a similar MoA appear likely to be close competitors. However, the evidence also indicates that other significant factors, including efficacy and safety, impact how closely two pipeline treatments are likely to compete. These factors can only be established in clinical trials.

Competitive constraints

89. The Merged Entity is more likely to have the incentive to continue developing potentially competing products when a large proportion of the demand it expects to satisfy with those products is likely to be 'stolen' from other competitors (rather than captured by the other Party), or comes from new or previously unmet demand.[121]

90. In assessing the constraint posed by competing suppliers post-Merger, the CMA has considered:

(a) the Parties' submissions;

(b) evidence of competitors active in the field;

(c) evidence from internal documents; and

(d) third party views.

91. As explained above, in the absence of clinical data to the contrary, the CMA believes that two products with a similar MoA are more likely to be close competitors than if they had a different MoA. However, factors such as efficacy and safety are also significant in determining closeness – in addition to MoA – and can only be established in clinical trials. For this reason, the

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[120] One clinician told the CMA: 'the Parties' pipeline drugs are still at an early stage of development. It is therefore too early to know whether these drugs are promising or not and to what extent they will closely compete. Should they reach the market, they could potentially be used in different settings of patients depending on their exact profile.' Note of call with [✂], 22 April 2021, paragraph 18. Another clinician stated: 'it is difficult to predict what the clinical benefit or consequences would be of combining two drugs or choosing to use one drug over the other. Sometimes you think a particular drug will be effective for a particular disease, on the basis of its biological profile or pathway, and it does not work in practice.' Note of call with [✂], 29 April 2021, paragraphs 32 and 33.
[121] Merger Assessment Guidelines, paragraph 5.19(b).

CMA considers in its assessment the constraint from all pipeline products (ie not only those that target a particular MoA).

Parties' views

92. The Parties submitted that, even if both Dizal's DZD4205 and Alexion's cerdulatinib are successfully brought to market by the Merged Entity, they will compete with at least ten other treatments with several different MoAs that are currently in development for the treatment of PTCL in the UK.[122] This includes at least six other pipeline assets that are currently expected to be on the market by the time cerdulatinib and DZD4205 could be launched.[123] The Parties submitted that their products are not expected to have a unique competitive advantage over other marketed or pipeline treatments and, in any event, the Parties' products are at an early stage of clinical development and future competition would be highly speculative.[124]

Competitors active in the field

93. The CMA has identified at least 11 other PTCL treatments, based on evidence from the Parties and third parties, which are set out in Table 3 below. Two of these are already-marketed products available in the UK.[125] With the exception of Adcetris (brentixuman vedotin), which is approved for a particular PTCL subtype, the other PTCL treatments listed in Table 3 below target the overall PTCL patient population.

Table 3: Other PTCL treatments

[✂]

Source: Information provided by Parties, as updated with information from other suppliers (where available).
[✂]

Internal documents

94. The CMA found that the Parties monitor a number of products (marketed and in development) for the treatment of PTCL, all of which are based on different MoAs. The Parties' internal documents also show that generally, while no particular focus is given to particular competitors and/or their products,

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[122] Merger Notice, 24 May 2021, paragraph 478.
[123] Furthermore, the Parties submitted that the products of the Merged Entity could also face competition from other off-label products. Though off-label products are not commonly used for the treatment of PTCL, there is no Standard of Care for relapse/refractory patients and the treatment paradigm simply recommends that relapsed patients should be enrolled in clinical trials.
[124] See for example Merger Notice, 24 May 2021, paragraph 594.
[125] For completeness, in the US, the local authorities have (conditionally) approved four other products for relapse and refractory patients: pralatrexate; romidespin; brentuximab; belinostat. These products are not available in the UK. See for example, Document titled [✂] submitted by AstraZeneca in response to the CMA's section 109 Notice of 28 April (**s109**), [✂].

comparisons with already approved products (including those that are only available in the US and Japan) are common, including products with different MoAs. For example:

(a) In a presentation to Alexion's [✂] Alexion lists 12 suppliers with assets at Phase II clinical trials in its [✂].[126]

(b) In an [✂] presentation on [✂] from [✂], AstraZeneca identifies six [✂] in PTCL (outside of Japan and China).[127] In this same presentation, AstraZeneca also points to four already approved products for the treatment of PTCL in the US, including Brentuximab which [✂].[128]

(c) Further, AstraZeneca's internal documents generally indicate that it considers competition is increasing in PTCL.[129]

Third party views

95. Competitors considered that there to be a strong level of pipeline activity in the treatment of PTCL. A view shared by a number of competitors was that the market was 'competitive' with a 'wide range of medicines' that may be used either alone or in various combinations.[130]

96. This view was also shared by clinicians. For instance, one clinician described 'a rising number of pipeline treatments targeting PTCL.'[131] Similarly, another told the CMA that there is 'currently momentum in this space where no one drug is key. In other words, there are few companies exploring the JAK pathway and so if this strategy proves to be effective it will move forward with or without any one or two of the Parties' drugs.'[132] A third clinician pointed to 'three or four interesting and potentially promising drugs in the PTCL pipeline.'[133]

97. The evidence the CMA received from competitors and clinicians was generally consistent with the proposition that neither DZD4205 nor cerdulatinib are perceived as particularly promising relative to other products in the pipeline. For example, one supplier rated DZD4205 and cerdulatinib as

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[126] This includes [✂]. For completeness, the CMA notes that [✂]. See document titled [✂] submitted by Alexion in response to the s109, [✂].
[127] This includes [✂]. Response to CMA RFI 1, [✂].
[128] Annex 19 to Response to CMA RFI 1, Slide 55.
[129] For example, in an internal document assessing the Merger, AstraZeneca considers that there is [✂]. Document titled [✂], submitted by AstraZeneca [✂]. Another AstraZeneca internal document assessing the commercial opportunity in PTCL treatment more generally provides [✂]. Document titled [✂] submitted by AstraZeneca in response to the s109 [✂].
[130] Response to CMA questionnaire by [✂], page 31. See also Response to questionnaire by [✂], page 39.
[131] Note of call with [✂], 19 April 2021, paragraph 14.
[132] Note of call with [✂], 14 June 2021, paragraph 16.
[133] Note of call with [✂], 22 April 2021, paragraph 12.

equally or less promising than [✂][134] competing pipeline products, including [✂].[135] Similarly, one clinician explained that 'it is hard to pick a standout in T-cell lymphoma.'[136] Another opined that, given their MoA, these products are 'not known to be very interesting' as regards PTCL.[137]

98. None of the third parties that responded to the CMA's investigation expressed concerns about the impact of the Merger on competition in respect of PTCL treatments.[138]

Conclusion on competitive constraints

99. Based on the evidence available, there are a large number of other products currently in development for the treatment of PTCL, in addition to those already marketed. Furthermore, the evidence does not suggest that Dizal's DZD4205 or cerdulatinib would be any more promising than those other products in development (with some evidence indicating that they may be less promising). Accordingly, the CMA believes that the Merged Entity will face sufficient competitive constraint on innovation and in relation to potential marketisation of their products for the treatment of PTCL.[139]

Conclusion on horizontal unilateral effects in the treatment of PTCL

100. For the reasons set out above, the CMA considers that the Merged Entity will face sufficient competitive constraints from several alternative suppliers of products for the treatment of PTCL. Accordingly, even if the Parties were to ultimately discontinue the development of one or more of their pipeline treatments for PTCL, there would be a sufficient number of products in the pipeline to ensure competition on innovation is not substantially lessened.

101. Accordingly, the CMA considers that the Merger does not give rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in relation to the treatment of PTCL.

Horizontal unilateral effects in complement therapeutics

102. The CMA has assessed whether the Merged Entity would have an incentive to abandon or reduce R&D efforts in relation to complement therapeutics,

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[134] [✂].
[135] Response to questionnaire by [✂], page 41.
[136] Note of call with [✂], 5 May 2021
[137] Note of call with [✂], 29 April 2021, paragraph 30.
[138] See for example, Response to CMA questionnaire by [✂] 'In my view, this acquisition would have no materially adverse effect on competition.'
[139] In the light of the CMA's findings, it was not necessary to conclude on whether the business case for making the investments was already marginal.

giving rise to a realistic prospect of an SLC in the development of products targeting the complement system globally.

103. Analogous to the CMA's assessment of the Merger Entity's R&D efforts in respect of one or more of its pipeline PTCL products set out above, this could be a profitable strategy post-Merger if the R&D undertaken by AstraZeneca and Alexion is expected to lead to therapies for the same diseases (and other technologies are less well-suited to treating these diseases).

104. This would be concerning if: (i) there are a limited number of firms with R&D activities in relation to complement therapeutics; or (ii) despite a number of firms with relevant R&D activities, AstraZeneca was relatively promising or well-placed among them.

105. The evidence indicates that a very large number of firms[140] are engaged in complement therapeutics and that those firms will provide a competitive constraint post-Merger. Whilst Alexion appears to have a strong presence, the evidence indicates that [✂] to raise competition concerns.[141]

106. Furthermore, the large majority of competitors did not raise any concerns with the Merger in relation to the complement system.[142] Indeed, many competitors were of the view that AstraZeneca and Alexion did not compete or were, at most, distant competitors in relation to the complement system.[143] [✂].[144]

Conclusion on horizontal unilateral effects in complement therapeutics

107. For the reasons set out above, the CMA considers that the Merged Entity will face sufficient competitive constraints from several alternative suppliers of products targeting the complement system. Accordingly, the CMA believes that the Merger does not give rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in relation to complement therapeutics.

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[140] The evidence suggests at least 25 firms are engaged in R&D activities in relation to the complement system. See for example, Document titled [✂], submitted by Alexion in Response to RFI 2. For completeness, the CMA contacted all 25 firms identified as having activities in relation to the complement system and received responses from [✂] of these entities – all of which confirmed that they were active in complement therapeutics.
[141] The CMA requested 'all Internal Documents which discuss AstraZeneca's strategy for the complement pathway.' A total of [✂] documents relating to the complement system were provided all of which [✂]. This evidence suggests that AstraZeneca [✂].
[142] The CMA contacted all 25 firms identified as having activities in relation to the complement system and received responses from [✂] of these entities. Out of the [✂] responses received, [✂] competitors did not have concerns with the Merger. This represents [✂] of responses and includes the following market participants: [✂].
[143] This includes, for example, [✂].
Furthermore, other market participants did not consider AstraZeneca an active player in respect of the complement system space. This includes, for example, [✂].
[144] Alexion considers its 'main' competitors or products as [✂]. The list of 'main' complement inhibitor competitors includes [✂]. Response to [✂], paragraph 15.

Third party views

108. The CMA contacted competitors of the Parties, as well as clinicians with expertise in the treatment of PTCL.[145] None of the third parties contacted by the CMA raised concern in relation to the treatment of PTCL. Two third parties noted the Merger would create a stronger competitor in complement therapeutics.[146] Another third party, [✂], noted [✂].[147] However, the CMA did not identify a merger-specific effect in this respect.

109. Third party comments have been taken into account where appropriate in the competitive assessment above.

Decision

110. Consequently, the CMA does not believe that it is or may be the case that the Merger may be expected to result in an SLC within a market or markets in the United Kingdom.

111. The Merger will therefore **not be referred** under section 33(1) of the Act.

Alex Olive
Director, Mergers
Competition and Markets Authority
14 July 2021

[145] For completeness, the CMA also contacted clinicians with expertise in relation to FL and LN.
[146] Response to CMA questionnaire by [✂] and response to CMA questionnaire by [✂].
[147] Response to CMA questionnaire submitted by [✂].