Annex 6 – Representations on abuse

Annex 6.1: The Unfair Limb – Economic value – therapeutic value

6.1 Section 5.E.II.a.ii (*Therapeutic value to patients*) of this Decision sets out the CMA's conclusion that the therapeutic value of Liothyronine Tablets is likely to be no higher than that of Levothyroxine Tablets, which were priced significantly below the Cost Plus of Liothyronine Tablets during the Infringement Period.

6.2 The Parties argue that the CMA's assessment based on Levothyroxine Tables is inappropriate and have proposed alternative approaches. HgCapital argues in favour of an assessment based on the 'quality adjusted life year' (QALY); Cinven argues that Levothyroxine Oral Solution would be a more appropriate comparator.

I. QALYs

6.3 HgCapital argues that QALYs are '*[a]n objective quantitative method with which to assess the economic value contributed by different drugs*'.[1] It says that '*[w]hen considering new treatments NICE will generally accept treatments which provide a QALY at a cost of less than £20,000 as cost-effective*'.[2]

6.4 The CMA does not consider that a methodology which, as noted by HgCapital, is generally used to assess the cost-effectiveness of new treatments, is an appropriate way of assessing the economic value of a product which was developed in the 1950s (see paragraph 3.21 of this Decision). In the UK, the QALY is a measure which is used to support NICE's health technology appraisals. These technology appraisals are intended to cover '*all <u>new</u> significant drugs and indications'*.[3]

6.5 This is reinforced by NICE guidance, which indicates that QALYs are used '*to assess a technology's clinical and cost effectiveness for a specific indication […] compared with the appropriate comparator(s)*'.[4] In other words, they are used for comparing new technologies with pre-existing technologies. This suggests that QALYs are unsuitable for assessing the economic value of

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[1] Document LIO7798, HgCapital RSSO-2019, paragraph 215.
[2] Document LIO7798, HgCapital RSSO-2019, paragraph 216.
[3] Document PAD212, NICE: *'Guide to the processes of technology appraisal'*, April 2018], paragraph 2.1.1. See also paragraph 2.1.5 which states that the University of Newcastle '*notifies NICE about key <u>new</u> <u>and emerging</u> healthcare technologies that might be suitable for NICE technology appraisal*' (emphasis added).
[4] Document PAD193, NICE '*Guide to the methods of technology appraisal 2013*', paragraph 1.3.2; see also paragraph 3.1.2.

Liothyronine Tablets, which as noted above have been available since the 1950s.

6.6 HgCapital's proposed application of the QALY as a theoretical yardstick for economic value is inappropriate. NICE does not use QALYs on their own, but appraises health technologies taking account of a range of other issues, including:

- '*[T]he impact of having a condition or disease, the experience of undergoing specific treatments for that condition, and experience of the healthcare system for that condition',*
- '*[O]rganisational issues that affect patients, carers or healthcare providers',*
- '*NICE's legal obligations on equality and human rights',*
- '*[T]he requirement to treat people fairly*'.[5]

6.7 Even if a figure could be arrived at using a QALY as a metric, it would be wrong in principle to do so. The Court of Appeal in *Phenytoin* has explained that economic value is '*what customers value and will reasonably pay for.*'[6] As noted at paragraph 5.298 of this Decision, even for relatively low volume products such as Liothyronine Tablets, other generic drugs very rarely cost the NHS more than £10 per pack, and the vast majority cost less than £3 per pack. Whilst a QALY might be able to calculate a theoretical maximum that a customer might pay *in extremis* for Liothyronine Tablets (or these other generic products), this figure would not represent the amount the customer would reasonably pay for a long off-patent drug, which is instead likely to be an amount close to costs of production.

II. Levothyroxine and the PPRS

6.8 Cinven has argued that the prices of Levothyroxine Tablets are not fully reflective of the economic value of the product because the pricing of Advanz's branded version of the product (Eltroxin) was directly constrained by the PPRS throughout the Infringement Period and the pricing of non-branded versions was indirectly constrained owing to the price regulation on Eltroxin.[7]

6.9 The CMA has described Advanz's '*price optimisation*' strategy in detail in section 5.B of this Decision. The first stage of Advanz's price optimisation

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[5] Document PAD193, NICE '*Guide to the methods of technology appraisal 2013*', paragraph 3.1.4.
[6] Phenytoin CoA [2020] EWCA Civ 339, paragraph 171 (emphasis added).
[7] Document LIO12052, Cinven RSSO-2020, paragraph 7.25.

strategy was to identify products which were: (i) within the PPRS; and (ii) within the third stage of the drug lifecycle with no competition and strong entry barriers. Advanz would have had a strong financial incentive to de-brand and then raise the price of Eltroxin if it had been profitable to do so. The fact that Advanz refrained from de-branding Eltroxin, combined with the very low volumes of Eltroxin sold by Advanz, strongly indicates that – rather than its presence within the PPRS – other market characteristics acted to constrain its pricing of Eltroxin.[8] Further, evidence relating to the pricing of Levothyroxine Tablets between 2007 and 2018 indicates that it is competition from Teva which is the primary reason why the pricing of Levothyroxine Tablets is low (see paragraph 3.199 and Figure 3.5 of this Decision). Accordingly, the CMA rejects Cinven's submission.

III. Levothyroxine Oral Solution

6.10 The CMA concludes that there are no demand-side factors which would add (or materially add) to the economic value of Liothyronine Tablets, meaning that the economic value of Liothyronine Tablets is captured in the Cost Plus assessment. The CMA concludes that the primary driver of price for a product in the third phase of the drug lifecycle is the degree of competition faced by the suppliers, rather than the therapeutic value of a product. For completeness, the CMA has considered whether the patient benefit, or therapeutic value, of a drug may be an example of '*additional benefits*' or '*enhanced value*' which might lead to a product being able to command a pricing premium. The CMA considers that Levothyroxine Tablets are a relevant comparator for this purpose and finds that the therapeutic value of Liothyronine Tablets is likely to be no higher than that of Levothyroxine Tablets, which were priced significantly below the Cost Plus of Liothyronine Tablets during the Infringement Period.

6.11 Cinven argues that the CMA's comparison with Levothyroxine Tablets is inappropriate,[9] and that:

> '*A more relevant comparator for the niche Liothyronine tablet may be the similarly niche oral sugar-free formulation of Levothyroxine. Whilst both address the same indication (hypothyroidism) both have*

[8] In fact, Advanz *did* de-brand Eltroxin in 2013, but re-introduced the brand in 2016. However, volumes of Advanz's branded product remain a fraction of its sales of its unbranded product (40,000 packs of Eltroxin in 2017 compared to 12.5 million packs of unbranded Levothyroxine Tablets sold by Advanz alone in 2017). See paragraph 3.197 of this Decision.
[9] Document LIO12052, Cinven RSSO-2020, paragraphs 7.26-7.30.

small volumes and more complicated manufacturing processes than the tablet formulation of Levothyroxine.'[10]

6.12 CRA, on behalf of Cinven, has carried out a per dose comparison of the prices of Liothyronine Tablets and Levothyroxine Oral Solution. It bases the price of Levothyroxine Oral Solution on the August 2020 Drug Tariff prices.[11,12]

6.13 The CMA has gathered evidence regarding Levothyroxine Oral Solution to assist it in evaluating Cinven's representations. Having reviewed this evidence, the CMA concludes that Levothyroxine Oral Solution is not a suitable comparator for assessing the therapeutic value of Liothyronine Tablets. In particular, the evidence shows significant demand-side differences between them. The primary driver behind the prescribing of the Levothyroxine Oral Solution (as opposed to Levothyroxine Tablets) is the *format* of the product (i.e. the fact that it is a solution which can be taken by patients who have difficulties swallowing tablets) rather than the product's therapeutic effect. Since Liothyronine Tablets are by their nature not in an oral solution format, the Levothyroxine Oral Solution does not serve as a suitable comparator. In addition, there are significant supply-side differences in the manufacturing processes between Levothyroxine Oral Solution and Liothyronine Tablets which cast further doubt on the relevance of Levothyroxine Oral Solution as a comparator.

a. Levothyroxine Oral Solution – Background

6.14 The levothyroxine molecule, most commonly prescribed in tablet form, is also available as an oral solution. While containing the same active pharmaceutical ingredient as the tablet formulation, the oral solution is prescribed almost exclusively to patients who cannot take medicine in tablet format.[13]

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[10] Document LIO12055, Third Cinven CRA Report, paragraph 49.
[11] Document LIO12055, Third Cinven CRA Report, paragraph 50 and table 3. Cinven has carried out a price comparison per dose of Levothyroxine Oral Solution and Liothyronine Tablets. Given that the differences between Liothyronine Tablets and Levothyroxine Oral Solution are sufficient for the CMA to conclude that Levothyroxine Oral Solution is not a suitable comparator, the CMA does not carry out its own price comparison. However, the CMA notes that, whereas Cinven's price comparison is between the NHS Reimbursement Price of Levothyroxine Oral Solution and the ASP of Liothyronine Tablets, the ASP of Levothyroxine Oral Solution is considerably lower than the NHS Reimbursement Price. See: Document LIO12116, Zentiva UK response to s.26 notice dated 15 October 2020, '*Annex 2 to Zentiva's s.26 response*'; Document LIO12126, Wockhardt response to s.26 notice dated 15 October 2020, '*Wockhardt data template 20201015*'; Document LIO12118, Teva UK's response to s.26 notice dated 15 October 2020, '*Annex 1 (Question 2)*.xlsx'; Document LIO12125, BCM's response to s.26 notice dated 15 October 2020, '*Annex 1 to BCM's response to s.26 notice dated 15/10/2020 – Levothyroxine oral solution average selling price*'; Document LIO12123, Advanz's response to s.26 notice dated 15 October 2020, '*Case 50395 – 20201015 Advanz – Annex.xlsx*'.
[12] The CMA also notes that Levothyroxine Oral Solution is a Category A drug unlike Levothyroxine Tablets and Liothyronine Tablets, which are both Category M drugs. The reimbursement prices of Category A drugs are set on a different basis to Category M drugs.
[13] Document LIO12119, '*Note of call with Simon Pearce (Newcastle University)',* 13 October 2020, paragraphs 6-7.

6.15 Levothyroxine Oral Solution is manufactured and/or supplied as an unbranded generic by Advanz,[14] Wockhardt, BCM, Zentiva UK and Teva UK. All firms supply the product in the following strengths: 25mcg/5ml, 50mcg/5ml and 100 mcg/5ml. Zentiva UK is also the sole supplier of an additional strength of 125mcg/5ml.

6.16 Prior to Advanz's entry, Levothyroxine Oral Solution was manufactured by a single firm (Kappin Ltd) which ceased production in 2009. Advanz saw a market opportunity and began development of Levothyroxine Oral Solution,[15] obtaining an MA on 4 May 2012.[16] As can be seen from Table A6.1 below, competition soon followed from Teva, with the majority of competing products entering the market after June 2016.

Table A6.1: Entry of firms manufacturing and/or supplying Levothyroxine Oral Solution

Name of Firm	Levothyroxine Oral Solution strengths	MA Approval	Distribution Began
Mercury Pharmaceuticals Limited	25mcg/5ml, 50mcg/5ml, and 100mcg/5ml	4 May 2012	25mcg/5ml and 50mcg/5ml: June 2012 100mcg/5ml: August 2012[17]
Teva UK Limited	25mcg/5ml, 50mcg/5ml, and 100mcg/5ml	24 May 2012	February 2013[18]
Wockhardt UK Limited	25mcg/5ml, 50mcg/5ml, and 100mcg/5ml	18 February 2016	25mcg/5ml and 50mcg/5ml: 23 June 2016 100mcg/5ml: 18 January
Zentiva Pharma UK Limited	25mcg/5ml, 50mcg/5ml, 100mcg/5ml and 125mcg/5ml	24 October 2016	August 2017[20]
BCM Specials Limited and BCM Limited	25mcg/5ml, 50mcg/5ml, and 100mcg/5ml	3 May 2018	August 2019[21]

Source: CMA analysis of third party responses

[14] Advanz initially sold the Levothyroxine Oral Solution under the brand name, 'Eltroxin', but decided to de-brand the product. By January 2014, all Advanz formulations of the oral solution were sold under the generic name 'Levothyroxine Oral Solution'. See document LIO0389, Internal Advanz email from [Advanz Commercial Services Director] to [Advanz General Counsel and Secretary] dated 11 February 2014, '*FW: Brand To Generic*'.
[15] Document LIO0493, '*Project Asclepius - Initial draft_Exec Sum and storyline_v6.5.pdf*', page 35.
[16] Document LIO12069, MHRA's response to the CMA's s.26 notice dated 7 September 2020, '*Levothyroxine oral solution.xls*'.
[17] Document LIO12122, Advanz's response to question 5 of the CMA's s.26 notice dated 15 October 2020.
[18] Document LIO12117, Teva UK's response to question 1 of the CMA's s.26 notice dated 15 October 2020.
[19] Document LIO12106, Email from [✂] (Wockhardt) to [✂] (Wockhardt) dated 29 September 2020.
[20] Document LIO12115, Zentiva UK's response to question 1 of the CMA's s.26 notice dated 15 October 2020.
[21] Document LIO12124, BCM response to s.26 notice dated 15 October 2020.

b. Levothyroxine Oral Solution – demand-side factors

6.17 As set out at paragraph 5.87 of this Decision, the economic value of a product may exceed Cost Plus as a result of factors including any '*particular enhanced value from the customer's perspective*'.[22]

6.18 The CMA held a meeting with Professor Simon Pearce, a Professor of Endocrinology at Newcastle University and Consultant Endocrinologist at the Newcastle-upon-Tyne Hospitals NHS Foundation Trust[23] to understand better the factors which drive the prescribing of Levothyroxine Tablets, Levothyroxine Oral Solution and Liothyronine Tablets.

6.19 Professor Pearce told the CMA that from his perspective, Levothyroxine Oral Solution was not *'the alternative to liothyronine tablets*'.[24] Professor Pearce explained:

(a) Liothyronine Tablets tend to be prescribed to patients for whom Levothyroxine Tablets are ineffective.[25]

(b) In contrast, Levothyroxine Oral Solution is prescribed to patients for whom the active ingredient within the tablet is effective, but who either: (i) would have difficulty swallowing a tablet, such as young children, the elderly and individuals with disabilities; or (ii) are allergic to one or more of the non-active ingredients in the tablet form.[26]

6.20 Professor Pearce made clear that it is the format of the product (which is easier for some patients to swallow) which drives the decision to prescribe the oral solution, rather than a difference in the therapeutic effect. He further explained that prescribers would generally avoid prescribing Levothyroxine Oral Solution.[27] In this regard:

(a) Levothyroxine Oral Solution carries a greater risk that a patient may accidently overdose. Levothyroxine Tablets allow for patients to take a single, consistent dose of the molecule each day (e.g. one 100mcg tablet every day). By contrast, a patient taking the oral solution will measure their own dosage every day, which can be complicated by the fact that a pharmacist may not always dispense the same strength solution. This means that the patient will

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[22] *Albion Water II* [2008] CAT 31, paragraph 222.
[23] Professor Pearce is also President of the British Thyroid Association, an executive committee member of the European Thyroid Association and Editor-in-Chief of the European Thyroid Journal.
[24] Document LIO12119, '*Note of call with Simon Pearce (Newcastle University)',* 13 October 2020, paragraph 4.
[25] Document LIO12119, '*Note of call with Simon Pearce (Newcastle University)',* 13 October 2020, paragraph 13.
[26] [✂], Director of Research and Development at Wockhardt, noted that Wockhardt considered Levothyroxine Oral Solution to be beneficial for '*certain patient groups (e.g. children / elderly)* [who] *cannot take tablets*' see: document LIO12112, '*Note of call with* [✂] *(Wockhardt)*; 28 September 2020, paragraph 12.
[27] Document LIO12119, '*Note of call with Simon Pearce (Newcastle University)',* 13 October 2020, paragraph 7.

need to vary their dosage depending on the strength of the solution provided,[28] leading to an increased risk of error.

(b) Levothyroxine Oral Solution is generally '*significantly more expensive than tablets*'.

6.21 This is consistent with the approach taken by CCGs which instruct practitioners to *"consider whether [Levothyroxine Oral Solution] is absolutely necessary."*[29]

6.22 The CMA concludes that the demand-side factors underlying the prescribing of Levothyroxine Oral Solution are so different to those underlying the prescribing of Liothyronine Tablets that Levothyroxine Oral Solution is not a suitable comparator for assessing the therapeutic value of Liothyronine Tablets.

6.23 In any event, the fact that Levothyroxine Oral Solution and Levothyroxine Tablets have an identical therapeutic benefit (they are two formats for administering the same active substance) further confirms that therapeutic value is not in fact the driver of pricing in off-patent medicines (see the CMA's conclusion at paragraphs 5.208(a) and 5.211 of this Decision). In any case, even if it were accepted that therapeutic considerations drove the price premium which the oral solution commands over Levothyroxine Tablets, it would necessarily be the benefits of the oral solution *format* of the product which generates that pricing premium. However, Liothyronine Tablets are not sold in an oral solution format and so would not be expected to command any similar premium.

c. Levothyroxine Oral Solution – supply-side factors

6.24 Although the CMA considers that it is sufficient and appropriate for an assessment of therapeutic value to be based on demand-side considerations, it observes that there are also significant supply-side differences between Levothyroxine Oral Solution and Liothyronine Tablets.

6.25 The CMA disagrees with Cinven's contention that Liothyronine Tablets are '*more complex and difficult'* to manufacture than Levothyroxine Tablets.[30] The manufacturing process of Levothyroxine Tablets has many similarities to the manufacturing process for Liothyronine Tablets: both Liothyronine and Levothyroxine Tablets are difficult to manufacture and are considered '*non-*

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[28] A patient might generally take 5ml of the 100mcg/5ml strength solution but may need to vary this to 20ml if given a 25mcg/5ml strength solution, or to 10ml if given the 50mcg/5ml strength solution.
[29] See for example document LIO4656, '*Airedale, Wharfdale and Craven CCG_Liothyronine.04.05.17*', page 1.
[30] Document LIO12052, Cinven RSSO-2020, paragraph 7.34(a).

standard' for similar reasons; both products contain low levels of the active pharmaceutical ingredient per tablet which creates challenges in ensuring content uniformity; both products also have a sensitivity to light, moisture and temperature during the manufacturing process.[31] However, in some respects, Liothyronine Tablets may be less difficult to manufacture than Levothyroxine Tablets: the MHRA has said that Liothyronine Tablets are less prone to instability and less sensitive to process conditions than Levothyroxine Tablets.[32]

6.26 In a meeting with the CMA, Wockhardt (a manufacturer of both Levothyroxine Oral Solution and Levothyroxine Tablets) explained manufacturing issues relevant to oral solutions and tablets.

6.27 Wockhardt confirmed that there are problems that are unique to the manufacture of tablets (whether Levothyroxine or Liothyronine Tablets), which are not present in the manufacture of oral solutions and *vice versa*. Wockhardt explained that '*in general, oral solutions can be more unstable than tablets*'[33] and noted the following specific difficulties faced when manufacturing Levothyroxine Oral Solution:[34]

(a) There are problems with achieving the optimal pH in the solution which would avoid the degradation of the molecule.

(b) The presence of water during the manufacturing process creates additional issues. By contrast, tablets can be made in a completely dry environment.

(c) Due to the relatively low volumes of Levothyroxine Oral Solution sold, the product is produced in much smaller batch sizes. These small batch sizes mean that a manual manufacturing process is used which increases the cost of production. The low volume of output also means that the production process uses a '*relatively low speed pump*'. Wockhardt notes that it '*takes approximately a week to produce the 3,000* [100ml bottles].'[35]

6.28 Wockhardt started supplying varying strengths of Levothyroxine Oral Solution in February and June 2016, but it continues to experience difficulties in its manufacture. It has detected a problem involving the degradation of the oral solution which results in a shorter shelf-life. Although its Levothyroxine Oral Solution product has been on the market for over four years, Wockhardt

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[31] See: paragraphs 3.35-3.37 and 3.47 of this Decision which discuss the manufacturing process of Levothyroxine Tablets and Liothyronine Tablets in detail.
[32] Document LIO6884, MHRA's response to question 2 of the CMA's s.26 notice dated 5 July 2018.
[33] Document LIO12112, '*Note of call with* [✂] *(Wockhardt)*; 28 September 2020, paragraph 12.
[34] Document LIO12112, '*Note of call with* [✂] *(Wockhardt)*; 28 September 2020, paragraphs 8-9.
[35] Document LIO12112, '*Note of call with* [✂] *(Wockhardt)*; 28 September 2020, paragraphs 8-9.

continues to incur costs in the development of the oral solution as it investigates and attempts to rectify stability issues.[36]

6.29 This evidence shows that the manufacture of Levothyroxine Oral Solution is complex and these manufacturing complexities are different to those associated with the manufacture of Liothyronine Tablets, with a very different production process that presents different challenges. Moreover, there are particular difficulties affecting the manufacturing process for the oral solution that are not present in manufacturing the tablets.

[36] Document LIO12112, '*Note of call with* [✂] *(Wockhardt)*; 28 September 2020, paragraphs 14-15.

Annex 6.2: The Unfair Limb – Economic value – willingness to pay

6.30 Section 5.E.II.b of this Decision sets out the CMA's conclusion that Advanz's customers were not readily willing to pay a premium for Liothyronine Tablets.

6.31 Advanz has argued that the DHSC/NHS[37] '*acquiesced*' to its prices for Liothyronine Tablets:

(a) by approving those prices (principally through the NHS BSA); and

(b) by taking an informed decision not to intervene.[38]

I. Introduction and summary

6.32 Whether a customer was readily willing to pay a price that reflected the economic value of a product is relevant to whether an exploitative abuse has been committed. The correct place to deal with the perception of Advanz's customer(s) is therefore when considering economic value and specifically customer willingness to pay. The CMA has done this in section 5.E.II of this Decision.

6.33 However, Advanz argues that DHSC/NHS acquiescence is not relevant to dominance or to abuse.[39]

6.34 Advanz argues that *Genzyme Ltd v OFT* [2004] CAT 4 ('***Genzyme***') establishes a legal principle that where a customer acquiesces to a supplier's conduct, that supplier is not acting unilaterally, such that Chapter II does not apply.[40] On the basis of this principle, Advanz argues that because the DHSC/NHS had '*acquiesced*', Advanz did not act unilaterally when setting prices for Liothyronine Tablets.[41]

6.35 The CMA rejects this argument. The evidence does not support Advanz's claim that the DHSC/NHS '*acquiesced*' to Advanz's prices. In any event, *Genzyme* establishes no such principle. Advanz's argument is therefore wrong on the facts and in law.

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[37] Since their roles overlap (the NHS, through its CCGs, as 'customer' and the DHSC, as the Government body with responsibility for the NHS and generic drug pricing, as 'regulator'), the NHS and DHSC are referred to together as '*the DHSC/NHS*'.
[38] Document LIO7781, Advanz RSSO-2019, paragraph 1.6.2. Document LIO12043, Advanz RSSO-2020, paragraphs 3.7.2, 3.46-3.47. Document LIO6288, Advanz RSO, paragraph 4.23.3.
[39] Document LIO12043, Advanz RSSO-2020, paragraphs 3.8, 3.33 and 4.76. See also document LIO12198, Advanz's representations on the 2021 Letter of Facts, paragraphs 2.44 and 2.52.
[40] Document LIO7781, Advanz RSSO-2019, paragraph 1.6.2. Document LIO12043, Advanz RSSO-2020, paragraphs 3.8, 3.11, 3.12, 3.15, 3.27-3.28, 3.33, 3.48, 3.50 and 3.70.
[41] Document LIO6288, Advanz RSO, paragraph 4.23.3. Document LIO12043, Advanz RSSO-2020, paragraphs 1.20.3-1.20.4.

II. Advanz's argument is wrong on the facts

6.36 The CMA finds that Advanz's argument is wrong on the facts:

(a) First, Advanz's portrayal of its pricing of Liothyronine Tablets as '*open*', '*collaborative*' and consensual with the DHSC/NHS (and therefore not unilateral) is contradicted by its own contemporaneous documents;

(b) Secondly, Advanz's argument that the DHSC/NHS '*acquiesced*' to its prices is not supported by the evidence; and

(c) Thirdly, when viewed in context, the absence of DHSC/NHS intervention cannot be said to amount to '*acquiescence*' to Advanz's prices or to create a legitimate expectation for Advanz that its prices were 'acceptable' to the DHSC/NHS.

a. Advanz's portrayal of its pricing is contradicted by its own contemporaneous documents

6.37 Advanz states that it '*actively engaged with its customer, the DH/NHS, in the pricing of LIO*' and:

> *'worked openly and collaboratively with the DH/NHS at all times during the Alleged Infringement Period, including in relation to obtaining pricing approvals'*.[42]

6.38 Advanz argues that this means:

> *'[Advanz]'s price for LIO was not the result of unilateral action by [Advanz], instead it was the outcome of agreement between [Advanz] and the DH/NHS'.*[43]

6.39 These statements are contradicted by Advanz's own contemporaneous documents.

6.40 As explained in section 5.B of this Decision, Advanz's strategy was premised on leveraging its market power in relation to niche generic drugs. For example, Advanz's contemporaneous documents state that:

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[42] Document LIO7781, Advanz RSSO-2019, paragraphs 1.6.2 and 1.7.5. See also document LIO12043, Advanz RSSO-2020, paragraph 3.39: '*[Advanz] at all times dealt with the DH/NHS on an open and transparent basis in relation to its price for LIO*'.
[43] Document LIO6288, Advanz RSO, paragraph 4.23.3.

(a) It *'benefits from significant pricing power for products with limited or no competition and important clinical need*.'[44]

(b) *'the Company's unique portfolio of niche products with exclusive / semi-exclusive market positions shields it from the downward pricing spiral mechanism and provides room for continued price increases*'.[45]

6.41 Advanz's strategy was also premised on its understanding that the DHSC/NHS was not focused on such drugs. Instead, the DHSC/NHS was focused on the prices of patented drugs which in aggregate accounted for a greater proportion of its budget. This allowed Advanz to operate '*below the radar*' of the DHSC/NHS in relation to those drugs it identified for price optimisation. For example, Advanz's contemporaneous documents state that:

(a) *'Niche products (majority of [Advanz's] portfolio) are typically outside NHS pricing system (PPRS). Capturing it would require systemic changes, which NHS may not find worthwhile doing. Price control for products with few players is risky […] Any price control here may prove counterproductive for NHS if players withdraw from the market […] Niche market may be too small for future interest from NHS. Paying attention to niche segments may at best lead to very marginal additional savings for NHS'.* '*Current pricing levels are not high enough to attract unwanted attention*'.[46]

(b) Advanz's products '*are generally old and low volume and therefore fall below the reimbursement radar. In the UK such branded / niche low volume products benefit from a particularly beneficial reimbursement mechanism which, whilst effective for high volume products (which is what the NHS cares about) does allow for niche players to achieve good margins… Mercury therefore operates below the radar and capitalises on opportunities to achieve volume and pricing growth even in such a heavily regulated market … Reimbursement for drug manufacturers is controlled by a small group within the DoH … The focus is on high volume drugs (patent and off-patent) as this is where the absolute quantum of savings is higher: niche products are typically below the radar*'.[47]

(c) '*On-patent drug cost control will be focus for DoH with limited resources […]* '*System works on an aggregate basis … However on an individual drug basis*

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[44] Document LIO0765, '*CCM Pharma Confidential Information Memorandum Addendum.pdf*', page 23.
[45] Document LIO0221, '*Glacier Management Presentation_vFINAL.pdf*', page 13.
[46] Document LIO0493, Advanz's '*Project Asclepius - Initial draft_Exec Sum and storyline_v6.5.pdf*', page 40 (emphasis added). See also page 8: *'NHS cost control focus unlikely to be concentrated on small volume niche segments which would have minimal impact … Price control for drugs with few (1-3) competitors poses a risk of no supply if players exit*'; Document LIO3830, '*DRAFT - Concordia Corporate Presentation_09.13.16.pdf*', page 13; and Document LIO0794, '*20150802 Atoll Management Presentation vDRAFT.pdf*', page 65.
[47] Document LIO6490.3, *'Annex 2.1 - Minutes of a meeting of IC dated 2 July 2012*', pages 3, 6 and 8.

where there in [sic] no/little competition allows drug producers to increase prices and margin – this is the key element for [Advanz] with its niche portfolio'.[48]

(d) Advanz's drugs were therefore '*not the main focus of healthcare cost reduction initiatives*'.[49] Advanz described its portfolio as '*typically free from pricing limitations imposed by Payors (e.g. NHS in UK)*'. For '*non-PPRS*' drugs '*there is no regulatory price ceiling*'.[50]

6.42 Liothyronine Tablets were a paradigm of such drugs. Indeed, Advanz's investor materials frequently cited its pricing of Liothyronine Tablets as a case study of its strategy in practice. For example, Advanz's contemporaneous documents state that:

(a) Advanz '*has leveraged the favorable market dynamics to deliver 20-50% YOY [year on year] price increase for Liothyronine Sodium in UK … Liothyronine Sodium does not have any price ceiling being a non-PPRS drug. Further [Advanz] is the exclusive marketer of this drug in UK.*'[51]

(b) '*[Advanz] has a strong market position as the only supplier of Liothyronine tablets in the UK market. … Through its position as sole market provider in the UK, [Advanz] has strong pricing power. Over the last 3 years, [Advanz] has doubled the price of Liothyronine. Continued stable growth in historical volumes demonstrates the inelasticity of demand to the price increases*'.[52]

6.43 When implementing individual price increases for Liothyronine Tablets, Advanz was careful not to '*attract DH notice*'[53] or '*catch eyes of DH, due to price increase*'.[54]

6.44 This contemporaneous evidence contradicts Advanz's *ex post* argument that it set prices for Liothyronine Tablets in collaboration with the DHSC/NHS and

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[48] Document LIO0231, Advanz's '*Project Glacier Lenders Presentation_NOTES.pdf*', slide 16. See also Document LIO0232, Mercury Pharma materials presentation, September 2012, slides 9, 11 and 13.
[49] Document LIO0242, Advanz's '*Project Ampule Rating Agency Presentation_20121108_v03.pdf*' slides 14 and 20.
[50] Document LIO0493, Advanz's '*Project Asclepius - Initial draft_Exec Sum and storyline_v6.5.pdf*', page 7 (emphasis in original). See also page 28. See also document LIO0221, '*Glacier Management Presentation_vFINAL.pdf*', page 6.
[51] Document LIO0493, Advanz's '*Project Asclepius - Initial draft_Exec Sum and storyline_v6.5.pdf*', page 58. See also Document LIO0455, '*AMCo Sep14 - RAP_Final.pdf*', page 32; Document LIO0493, Advanz's '*Project Asclepius - Initial draft_Exec Sum and storyline_v6.5.pdf*', page 11 ('*Continued niche pricing strategy to optimise growth, both in UK (e.g. Liothyronine)*'); and Document LIO0493, Advanz's '*Project Asclepius - Initial draft_Exec Sum and storyline_v6.5.pdf*', page 39. See also pages 21 and 38.
[52] Document LIO0740, '*Mercury Pharma Confidential Information Memorandum.pdf*', page 62; see also document LIO0221, '*Glacier Management Presentation_vFINAL.pdf*', page 30; and document LIO0250, '*Ampule Confidential Information Memorandum_Draft_v08.pdf*', page 47.
[53] Document LIO0275, Emails from [Advanz Commercial Services Director] to [Advanz CEO] dated 27 May 2013.
[54] Document LIO0279, Email from [Advanz employee] to [Advanz Commercial Services Director] dated 29 May 2013.

that its conduct was not unilateral. Advanz specifically targeted Liothyronine Tablets for price increases because of the unilateral market power it derived from its position as sole supplier and the lack of DHSC/NHS attention paid to niche generic drugs. Its success in implementing this strategy was a core selling point for investors.

6.45 Advanz's only response to this evidence was that '*The promotional material is investor-facing and naturally overstates [Advanz's] position on the market*'.[55]

b. Advanz's argument that the DHSC/NHS '*acquiesced*' to its prices is not supported by the evidence

6.46 Advanz argues that the DHSC/NHS '*acquiesced*' to its prices on the basis that:

(a) Advanz '*sought prior approval for its proposed prices from the DH/NHS*' through submissions to the NHS BSA,[56] and the DHSC (through the NHS BSA) informed Advanz that its prices were approved: '*the DH/NHS approved [Advanz]'s price on each occasion*';[57]

(b) In addition, Advanz '*pre-notified*' its prices to the DHSC/NHS through a voluntary '*circular to affected persons, including senior members of the DH's procurement team*'.[58] Those '*pre-notifications´* caused DHSC staff '*to assess the reasonableness of [Advanz's] proposed prices for LIO*';[59]

(c) Advanz informed the DHSC at meetings that it would be increasing prices across both its branded and unbranded portfolios to fund investment in its business and understood that the DHSC was '*happy*' that the price increases for Liothyronine Tablets were justified by that investment;[60]

(d) DHSC staff agreed '*to defend the price for LIO*' in response to a complaint;[61] and

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[55] Document LIO12043, Advanz RSSO-2020, paragraph 4.73.
[56] Document LIO7781, Advanz RSSO-2019, paragraph 1.6.2.
[57] Document LIO7781, Advanz RSSO-2019, paragraph 5.12. Document LIO12043, Advanz RSSO-2020, paragraphs 3.101 and 4.10. See also document LIO12198, Advanz's representations on the 2021 Letter of Facts, paragraphs 2.47 and 2.51.4.
[58] Document LIO7781, Advanz RSSO-2019, paragraphs 1.6.2 and 5.11. See also document LIO8044, witness statement of [Advanz General Counsel and Secretary] dated 11 February 2020, paragraph 34; document LIO6330, Cinven RSO, paragraph 5.102.
[59] Document LIO12043, Advanz RSSO-2020, paragraphs 4.30.1-4.30.2, 3.46.4, and 4.63.1-4.63.10.
[60] Document LIO7964, Advanz's SSO oral hearing transcript, pages 54-55, page 57 lines 19-25 and page 58 lines 1-3 and 21-22; Document LIO7858, Advanz's response to question 1 of the CMA's s.26 notice dated 11 September 2019. See also Document LIO8044, witness statement of [Advanz General Counsel and Secretary] dated 11 February 2020, paragraphs 43 and 47.
[61] Document LIO6288, Advanz RSO, paragraph 4.16.

(e) The DHSC '*intervened*' to increase the Drug Tariff Price of Liothyronine Tablets in April 2019, demonstrating its assessment that the product was worth more than the existing price.[62]

6.47 None of these statements is compatible with the contemporaneous evidence or with the accounts of the DHSC or NHS BSA.[63]

i. The NHS BSA

6.48 During the Infringement Period the NHS BSA Prescription Pricing Division ('**PPD**') (now NHS Prescription Services) calculated the monthly reimbursement prices in the Drug Tariff according to the process described in section 3.C.VI.d of this Decision. As part of this function the NHS BSA published the weekly NHS Dictionary of Medicines and Devices ('**dm+d**'), a repository of information to support the Drug Tariff.[64] It was in this context that Advanz notified the NHS BSA of its price increases for Liothyronine Tablets.

6.49 Advanz submitted notifications via a standardised template on an online platform, known as eMC In-Demand ('**eMC**'). In response to each notification, Advanz received an automated message from a third-party services firm called DataPharm (on behalf of the NHS BSA) stating:

> *'Thank you for your submission. This is now being sent to the NHSBSA PPD*
>
> *Your submission will now go through 2 checks. The first is an electronic check to ensure that all the data has been transmitted accurately. The second is by the NHSBSA PPD pharmacy team who will check the actual content of your submission'.*[65]

6.50 Advanz then received a further automated email stating:

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[62] Document LIO7781, Advanz RSSO-2019, paragraph 8.121.
[63] Advanz stated that the CMA should ask the DHSC '*why they were happy*' with the price of Liothyronine Tablets (Document LIO7964, Advanz's SSO oral hearing transcript, page 58 lines 21-22). The CMA held a meeting with DHSC officials to discuss Advanz's argument that the DHSC/NHS '*acquiesced*' to its prices on 25 September 2019. The account given by DHSC officials (Document LIO7865, Note of meeting between the DHSC and CMA dated 25 September 2019) is consistent with the contemporaneous evidence. It does not corroborate Advanz's argument. The CMA rejects Advanz's attempts to undermine the DHSC's account as '*ex post facto, informal and uncorroborated*' (document LIO12043, Advanz RSSO-2020, paragraphs 1.19 and 4.20-4.23, 4.42 and 4.63.16; Document LIO7970, Advanz's response to the First Letter of Facts, paragraphs 2.8-2.9). The CMA refers to the DHSC's account in the sections that follow as additional corroboration of the contemporaneous evidence. The NHS BSA's responses to s.26 notices and the note of its meeting with the CMA (discussed below) are used in the same way.
[64] Document LIO6622, the NHS BSA's response to question 2 of the CMA's s.26 notice dated 18 June 2018.
[65] See, for example, document LIO6284.7, Email from eMC to [Advanz employee] dated 11 March 2011.

'Your submission has now started the 2 stage process where the NHSBSA PPD will check and verify your data.

We will email you again to let you know whether your submission has been accepted or failed and whether the NHSBSA PPD has made any changes to your submission'.[66]

6.51 As these automated responses make clear, the NHS BSA's systems first conducted an electronic check to ensure that mandatory fields in the Excel sheet had been completed with intelligible entries.[67] After the second check (of '*the actual content of your submission*'), Advanz received an email from DataPharm headed '*completed submission*' which stated:

'We are pleased to inform you that the NHSBSA PPD has approved your submission. This submission is now complete.

…

If your effective date has passed, your data has already been added to the dm+d database.

…

If your effective date is in the future, your data will be added to the dm+d database on that date'.[68]

6.52 Advanz has described this second email as '*the final and explicit acceptance by the DH/NHS that a proposed price was acceptable to it*'.[69] It claims that under this process Advanz '*received an explicit "approval" of its proposed price*'.[70]

6.53 However, this process cannot be understood in the way Advanz claims and it is clear that none of the NHS BSA, the DHSC or indeed Advanz understood it in that way at the time.

6.54 The NHS BSA's 'approval' was limited to approving the notifications as validly completed for the information they contained to be included in the dm+d. It did not amount to approving the prices themselves as substantively acceptable to

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[66] See, for example, document LIO6284.10, Email from eMC to [Advanz employee] dated 11 March 2011.
[67] See document LIO6622, the NHS BSA's response to question 8 of the CMA's s.26 notice dated 18 June 2018.
[68] See, for example, document LIO6284.13, Email from eMC to [Advanz employee] dated 23 February 2016.
[69] Document LIO6288, Advanz RSO, paragraph 4.13.4.
[70] Document LIO12043, Advanz RSSO-2020, paragraph 3.101. See also paragraph 4.10 and document LIO12198, Advanz's representations on the 2021 Letter of Facts, paragraph 2.51.4, describing this as the DHSC/NHS '*corresponding with [Advanz] in writing to emphatically approve [Advanz]'s notified price increases*'.

the DHSC. This is clear from both the contemporaneous evidence and the subsequent explanations provided by the NHS BSA and the DHSC.

6.55 As the emails from the NHS BSA make clear:

(a) It was the '*submission*' that was approved, not the price itself.

(b) Further, approval of the submission could come either before or after the '*effective date*' of the price change. That is not consistent with the NHS BSA 'approving' 'proposed' price increases in advance.

6.56 The NHS BSA's own account of its role and interactions with Advanz is consistent with the contemporaneous evidence and with the account of the DHSC.[71] In a meeting with the CMA, the NHS BSA expressed surprise at the suggestion that it could be said to have substantively evaluated the price increases submitted through the eMD portal and accepted or rejected them on behalf of the DHSC depending on whether it thought the price increases were justified. The NHS BSA stated that it had never acted in a way that might give any reasonable company such an impression.[72]

6.57 The NHS BSA stated that the second check was:

> *'to ensure that the content of the completed fields makes sense and that the information has been provided to enable authoring of a product in dm+d in line with the dm+d Editorial Policy'.*[73]

6.58 The NHS BSA informed the CMA that any checks it conducted of the information provided were limited to ensuring that the price quoted was correct (i.e. it was the price intended by the supplier to take effect at the date indicated). Data were required to be inputted according to particular

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[71] The functions of the NHS BSA were set out in statutory instrument (The NHS Business Services Authority (Establishment and Constitution) Order 2005); directions (The Pharmaceutical and Local Pharmaceutical Services (Prescriptions, Payments and Listings) Directions 2013); and a framework agreement (Document PAD186, NHS BSA: '*Framework agreement between the Department of Health and NHS Business Services Authority 2014*'). Its role in relation to generic drug pricing was an administrative one, involving collecting information on prices to produce the Drug Tariff (see in particular paragraph 3(fa) of the Order; paragraph 3 of the Directions, and page 4 of the framework agreement). This does not extend to 'accepting' prices in the sense claimed by Advanz. The DHSC stated that the remit of the NHS BSA does not extend to cost control or price approvals for medicines, either generally or specifically in the context of Liothyronine Tablets. The NHS BSA has no authority to assess and accept a drug's selling price on behalf of the DHSC. Rather, its role is limited to verifying the accuracy of the pricing information provided. Although the DHSC is aware of the NHS BSA's process for gathering price information, it is not involved in the details and is not typically informed about notifications of generic drug prices to the NHS BSA under this process. Document LIO7865, Note of meeting between the DHSC and CMA dated 25 September 2019, paragraphs 12-14.

[72] Document LIO12193, note of call between CMA and NHS BSA dated 12 April 2021, paragraphs 11 and 12. Advanz submitted that this note had '*no probative value*' and that '*ex post facto statements by the DH/NHS must be treated with caution*' (document LIO12198, Advanz's representations on the 2021 Letter of Facts, paragraphs 2.38-2.40. See also document LIO12196, Cinven's representations on the 2021 Letter of Facts, paragraph 2.21). However, the NHS BSA's account is entirely consistent with the contemporaneous evidence and with the account of the DHSC.

[73] See document LIO6622, the NHS BSA's response to question 8 of the CMA's s.26 notice dated 18 June 2018.

conventions: e.g. ten pounds (£10) as '1000'. The NHS BSA's review was to ensure compliance with these conventions so that data could be inputted correctly. Its staff would also receive an automated 'flag' if an increase or decrease were greater than 20%. If this occurred, the NHS BSA would '*double check with the company that this price increase [or decrease] is correct*': for example, a company might have accidentally typed a pounds figure instead of a pence figure, e.g. '10' instead of '1000' when the price was to change to £10. Its team would also '*often check that the "effective date" that the company has indicated is definitely the correct "effective date"*'. The extent of these checks consisted of emailing the supplier '*with the intention of getting written confirmation that the price change is correct*'.[74] It did not extend to notifying the DHSC of the price change. Once a company confirmed that the price submitted was the price it intended, the NHS BSA team would not query it further. The NHS BSA in particular did not comment on whether a submission contained a 'good' or 'bad' price: it did not carry out any substantive review of the submissions it received.[75]

6.59 The NHS BSA further explained that its team would not have seen the automated responses Advanz received from DataPharm. NHS BSA staff would have seen only the details of the price notification, in tabular form.[76]

6.60 In response to the CMA's questions about the role of the eMC emails, the DHSC stated:

> *'The Department is aware of the NHS BSA's process behind updating the dm+d including the use of the In Demand [eMC] portal by companies; however, we have not been aware of the details, for example the wording of the notifications. Similarly, the Department is not typically informed about any notifications under this process. The NHS BSA uses the information to update dm+d, for example:*
>
> *To add a product; or*
>
> *To amend a price*
>
> *The NHS BSA is only checking for typos (confirming a decimal point is in the right place, particularly if there has been a sizeable*

[74] Document LIO6622, the NHS BSA's response to question 9 of the CMA's s.26 notice dated 18 June 2018.
[75] Document LIO12193, note of call between CMA and NHS BSA dated 12 April 2021, paragraphs 8, 9 and 12.
[76] Document LIO12193, note of call between CMA and NHS BSA dated 12 April 2021, paragraph 7. An example can be seen in document LIO6639, price change notification with effective date of 1 October 2013.

price increase) to make sure that the price submitted is what the company intended'.[77]

6.61 The DHSC's view was therefore that the NHS BSA's 'checking' was solely administrative: '*checking for typos*' in order to carry out its function of using this information to compile the dm+d. The DHSC was not aware of the content of Advanz's price notifications to the NHS BSA.

6.62 This second check of the '*actual content*' of Advanz's submissions was therefore not a check that the price increases were reasonable or acceptable to the DHSC. It was a check that the numbers provided were intelligible and suitable for inclusion in the dm+d. The references to '*whether your submission has been accepted or failed*' do not indicate that the NHS BSA was 'approving' Advanz's price increases on behalf of the DHSC. They relate to whether a particular template submission contained the requisite information for inclusion in the dm+d.[78]

6.63 Moreover, Advanz clearly understood this at the time:

(a) The notifications Advanz submitted consisted of a single-page form with the bare facts of the drug, new price and effective date. They contained no information on the reasons for price changes or any information that the NHS BSA (or anyone else) would need in order to assess whether the prices were 'acceptable' (such as costs information).[79]

(b) In response to an article in *The Times* in 2016 suggesting that the NHS BSA had challenged Advanz on particularly large price increases submitted through eMC (though without seeking '*explanation or justification*'), Advanz's General Counsel [✂] asked its staff to '*find the emails between AMCo and the NHS*'.[80] Advanz staff followed up to [Advanz General Counsel and Secretary] and [Advanz CEO], stating that:

'As regards Times's claim is concerned regarding "NHS CHALLENGING to AMCo" on large price increases [sic], I have attached a mail … where you will find a confirmation from NHS that computer picks up at random price changes, which they seek

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[77] Document LIO6878, the DHSC's response to question 4 of the CMA's s.26 notice dated 2 July 2018.
[78] See also document LIO12193, note of call between CMA and NHS BSA dated 12 April 2021, paragraph 13.
[79] See, for example, document LIO6634, NHS BSA's '*Q6a&b Submission Price Change - Message Id : 14834*'; document LIO6635, NHS BSA's '*Q6a&b Submission Price Change - Message Id : 14206*'; document LIO6636, NHS BSA's '*Q6a&b Submission Price Change - Message Id : 13456*'; document LIO6637, NHS BSA's '*Q6a&b Submission Price Change - Message Id : 13452*'; document LIO6638, NHS BSA's '*Q6a&b Submission Price Change - Message Id : 12328*'; document LIO6639, NHS BSA's '*Q6a&b Submission Price Change - Message Id : 11106*'; document LIO6640, NHS BSA's '*Q6a&b Submission Price Change - Message Id : 10719*'; and document LIO6641, NHS BSA's '*Q6a&b Submission Price Change - Message Id : 6536*'.
[80] Document LIO0823, Email from [Advanz General Counsel and Secretary] to [Advanz Commercial Services Director] dated 9 August 2016.

confirmation from the manufacturer not challenging the manufacturer decision on pricing

It is never a challenge from NHS, it is just a confirmation from NHS to be doubly sure about the price changes in DM+d'.[81]

6.64 Advanz was therefore well aware that the checks conducted by the NHS BSA were not a substantive review of its '*decision on pricing*'. Instead, they were simply for '*confirmation*' to be '*doubly sure*' that the information provided for the dm+d was accurate.[82]

ii. 'Pre-notifications' to 'the DH's procurement team'

6.65 Advanz did indeed send numerous '*price increase notification*' emails to recipients including DHSC and NHS staff during at least part of the Infringement Period.[83] However, as in relation to its notifications to the NHS BSA, there is nothing in these notifications to suggest that Advanz's purpose in sending them was to seek approval of the price increases from the DHSC, or that the entry into force of the new prices was contingent on any approval or other condition. In any event, whatever Advanz's reasons for sending them, there is no basis for Advanz's assertion that these notifications resulted in DHSC/NHS '*acquiescence*'. Indeed, on the face of the notifications, Advanz had already decided that the price increases would take place.

6.66 The notifications gave only perfunctory information. They consisted of a standard-form table containing information on the pack size; legal category; licence number; PIP code; bar code and new trade price for the specified drugs (which were not limited to Liothyronine Tablets) from the specified date. Information on the licence holder and/or relevant wholesalers was provided

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[81] Document LIO0824, Email from [Advanz Commercial Services Director] to [Advanz CEO] and [Advanz General Counsel and Secretary] dated 9 August 2016.

[82] Advanz stated that LIO0823 contradicted the statements of its staff in LIO0824 (document LIO12043, Advanz RSSO-2020, paragraph 4.17.5). Advanz also stated that LIO0823 showed that Advanz's '*senior management believed that the NHS-BSA had the power to challenge price increases, and that this belief was based on past dealings with the NHS-BSA*', citing what it presented as [Advanz General Counsel and Secretary]'s statements in the document (document LIO12198, Advanz's representations on the 2021 Letter of Facts, paragraph 2.50.4 and footnote 43). In fact, [Advanz General Counsel and Secretary] in LIO0823 simply said '*We need to find the emails between AMCo and the NHS: and then please email them as you find them*', before copying and pasting the story from *The Times*. It is LIO0824, the email Advanz's staff sent in response to that request, that contradicts the story from *The Times*.

[83] See, for example, document LIO2377, Email from [✂] to [Goldshield Head of Pharmaceuticals UK] and [Goldshield Head of Marketing Brands and Generics, India] and attachment dated 2 January 2008; document LIO2317, Email from [Advanz employee] to various recipients to dated 30 September 2008; document LIO2321, Email from [Advanz employee] to various recipients dated 31 March 2010; document LIO2319, Email from [Advanz Commercial Services Director] to various recipients dated 1 September 2011; document LIO2362, Email from [Advanz employee] dated 11 February 2015; documents LIO6284.19, LIO2319 and LIO2320, Email from [Advanz employee] to various recipients and attachment dated 11 February 2015.

below the table. The notifications said nothing about the reasons for the price increases or why they might be justified.

6.67 The DHSC has informed the CMA that these notifications were not requested by the DHSC. While Advanz copied DHSC staff in the supply team (not the procurement team) on these notifications, the reason for this was unclear to the DHSC. The DHSC recipients did not have a role to play in the pricing of Liothyronine Tablets and the DHSC did not review the notifications in order to assess whether Advanz's prices were 'acceptable'.[84]

6.68 Advanz's claim that these '*pre-notifications´* caused DHSC staff '*to assess the reasonableness of [Advanz's] proposed prices for LIO*'[85] is based solely on the fact that a DHSC staff member forwarded a single such notification, dated 31 May 2013 and covering 11 products including Liothyronine Tablets, to a colleague, asking: '*Can you have a look to see where these all sit in the Tariff and where not Cat A or M work with [a third DHSC staff member] to see if they are sole suppliers and if there is anything we can do to keep price down, ie ensure in Part VIII somewhere…*'.[86]

6.69 This exchange does not support Advanz's argument:

(a) First, it shows that, more than four years into the Infringement Period, the DHSC was not monitoring the price of Liothyronine Tablets or scrutinising the notifications in order to assess whether they were 'acceptable': the recipient of the notification had only '*a brief glance*' at the 11 products covered and further investigation was required to determine '*where these all sit in the Tariff*' and whether they were sold by sole suppliers.[87]

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[84] Document LIO7865, Note of meeting between the DHSC and CMA dated 25 September 2019, paragraphs 15-16.
[85] Document LIO12043, Advanz RSSO-2020, paragraphs 4.30.1-4.30.2, 3.46.4, and 4.63.1-4.63.10.
[86] Document LIO7893, Email between DHSC staff dated 3 June 2013.
[87] Advanz also submitted that the note of a meeting between the DHSC and the BGMA on 26 August 2016 (Document LIO0832) showed that Advanz was '*very aware that the DH was monitoring its LIO prices closely*' (Document LIO12043, Advanz RSSO-2020, paragraph 4.72.1). In fact, the document shows that as of August 2016 – less than a year before the end of the Infringement Period and more than seven years since the start of the Infringement – the DHSC's work to identify excessively priced generic drugs in response to concerns raised in the *Times* in 2016 was only just beginning: '*The Secretary of State was focused on recent comment in The Times, and had pressed officials to do something in response … all products that had been mentioned in The Times' articles would be likely to be assessed under their proposed system, as much for learning about them as anything else*'. The slides for the meeting noted: '*While we get signals on excessive prices we are not monitoring prices routinely and systematically. Therefore, we currently don't know what medicines go up dramatically in price and we cannot investigate what we do not know.*' The document therefore shows the opposite of what Advanz claims: the DHSC was not monitoring the prices of Liothyronine Tablets and was only just thinking about how it might go about it. This is corroborated by an internal DHSC email exchange of 21 September 2016 (Document LIO2405). While Advanz submitted that this exchange demonstrated that the DHSC was scrutinising its prices (Document LIO12043, Advanz RSSO-2020, paragraph 4.72.2), in fact it shows that the DHSC staff member was not familiar with the details of the product: '*Having looked in the BNF and discussed with NHS Digital, it appears the drug is a generic, comes in tablet and powder forms, 20 micrograms size and is POM.*'

(b) Secondly, there is no evidence that the DHSC assessed whether the price increase for Liothyronine Tablets was reasonable. As explained above, the notification did not give the DHSC the information it would need to make that assessment. In fact, the DHSC's perception was that the price increase was unlikely to be reasonable. The staff member who forwarded the notification noted that:

> *'These are big increases without them having to provide any justification – they have us over a barrel'.*[88]

iii. Advanz's meetings with DHSC staff

6.70 At the end of its oral hearing on the 2019 SSO, Advanz's General Counsel [✂] stated that, following criticism by the DHSC in 2010 of quality and supply issues with Advanz's portfolio (for example, drugs being regularly out of stock), Advanz made investments in supply chain and quality control. He indicated that this provided relevant context for the increases in the price of Liothyronine Tablets.[89]

6.71 The CMA asked Advanz to clarify these statements following the hearing. In response, Advanz stated that it held meetings with '*the DH procurement team*' in 2013 and 2015 '*to discuss AMCo's ongoing work to improve the supply of its branded and unbranded portfolio of products, how AMCo was improving supply, overcoming various technical issues, and the cost of the remedial initiatives in relation to AMCo's product portfolio. Both [slide packs for the meetings] refer explicitly to the work being conducted by AMCo in relation to LIO. The DH attendees were explicitly informed of the increasing costs to both parties of these remedial initiatives and of course were well aware of this from the various price increase pre-notifications that they were receiving from AMCo*'.[90]

6.72 [Advanz General Counsel and Secretary] later provided a witness statement stating that he had believed that:

> *'if the DH had any concerns, it would raise those with AMCo (for example, if it considered that the level of investment and improvement in the UK medicines no longer justified the level of*

[88] Document LIO7893, Email between DHSC staff dated 3 June 2013.
[89] Document LIO7964, Advanz's SSO oral hearing transcript, pages 54-55, page 57 lines 19-25 and page 58 lines 1-3 and 21-22.
[90] Document LIO7858, Advanz's response to question 1 of the CMA's s.26 notice dated 11 September 2019.

price increases, or more generally because it wanted to object to them).'[91]

6.73 As suggested by Advanz, the CMA put these points to the DHSC following the hearing on the 2019 SSO. The DHSC stated that:

(a) In 2010 and again in 2013 and 2015, it did indeed raise a number of concerns with Advanz regarding supply issues. This resulted in email correspondence between the DHSC and Advanz and two meetings between Advanz and DHSC officials, one in 2013 and one in 2015.

(b) The discussions at those meetings focused on supply issues (such as drugs that were out of stock) and quality control across a number of products in Advanz's portfolio, including Liothyronine Tablets.

(c) The role of the DHSC officials attending the meetings did not extend to the pricing of generic drugs in primary care.[92]

6.74 The contemporaneous documents corroborate the DHSC's account of the meetings it had with Advanz and do not support Advanz's account.

6.75 The records of the meetings consist of a slide pack for each (produced by Advanz) and a note of the 2013 meeting. No note of the 2015 meeting has been found. The records show that the discussions at these meetings focused on supply issues, especially ensuring continuity of supply for medicines. There is no reference to the pricing of Advanz's portfolio, either generally or specifically in relation to Liothyronine Tablets. The references to Liothyronine Tablets that do appear relate to supply issues, not to pricing.[93]

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[91] Document LIO8044, witness statement of [Advanz General Counsel and Secretary] dated 11 February 2020, paragraph 43. See also paragraph 47.
[92] Document LIO7865, Note of meeting between the DHSC and CMA dated 25 September 2019, paragraphs 4-9.
[93] The slide pack for the 2013 meeting covers AMCo's '*Supply Chain Strategy*' and '*Supply Action Plan*', including plans to improve AMCo's '*OOS*' (out of stock) rate and supplier relationships. The slides include a '*[c]ommunications proposal*' consisting of periodic reporting to the DHSC on supply chain issues. They note that Liothyronine Tablets are currently out of stock following recall of API by the supplier and explain AMCo's plans to find an alternative source of API and restock the product. They say nothing whatsoever about pricing, whether in relation to Advanz's portfolio generally or specifically in relation to Liothyronine Tablets (Document LIO7859, Annex 1 to Advanz's response to question 1 of the CMA's s.26 notice dated 11 September 2019). The note of the 2013 meeting refers to supply chain risks and mitigation, including the need to source a new API supplier for Liothyronine Tablets. It also contains nothing about pricing. The emphasis is on continuity of supply: in relation to Liothyronine Tablets the note states, '*all going well stock should be available by the end of May*'. The note goes on to discuss the need for notifications to the DHSC at an early stage in relation to potential shortages of critical medicines – not in relation to pricing (Document LIO2384, Note of meeting between the DHSC and Advanz dated 8 May 2013). The slide pack for the 2015 meeting includes a number of specific '*[p]roduct updates*'. In relation to Liothyronine Tablets, the slides refer to a '*[l]ong standing issue with non registered batch size and limited validation data*' and the steps AMCo proposed to take to resolve this to ensure a more robust production process going forwards. The slides conclude with some '*Common Themes*' on '*Challenges to Supply*', including '*Significant maintenance costs of AMCo protfolio [sic]*'. This general reference to costs across AMCo's portfolio is the only reference to costs in any of the materials. These slides, like the other materials, say nothing about

6.76 These meetings therefore do not provide relevant context for the increasing prices of Liothyronine Tablets. There is no evidence that the DHSC indicated at these meetings that it considered those prices justified by investments Advanz may have made in its portfolio generally. The meetings were with officials whose remit did not extend to the prices of Liothyronine Tablets, and concerned supply chain and quality issues, not pricing. That DHSC officials were aware that Advanz had made investments in its supply chain generally and that it would seek to recoup these costs cannot credibly be said to amount to approval of Advanz's specific price increases for Liothyronine Tablets, particularly when those prices were not discussed at all.[94]

iv. The DHSC did not 'agree to defend the price for LIO'

6.77 The internal DHSC email on which Advanz relies for its statement that '*The DH agreed to defend the price for LIO*'[95] is a July 2013 draft response to a complaint about the absence of alternative suppliers of Liothyronine Tablets. The author of the response was concerned primarily with supply issues and not with pricing. At the end of the draft response an attempt was made to offer a generic description of the type of factors that could – in the abstract – justify a higher price in the UK than in other jurisdictions. There was no assessment of whether Advanz's prices were in fact justified by those or other factors.[96]

v. The 2019 adjustment to the Drug Tariff Price of Liothyronine Tablets

6.78 The April 2019 adjustment to the Drug Tariff Price of Liothyronine Tablets is discussed in paragraphs 3.143 and 5.241 of this Decision. As explained in those paragraphs, the adjustment related to reimbursement prices, not selling prices; was not specific to Liothyronine Tablets; and did not reflect any assessment or approval of Advanz's prices (or those of any other drugs).

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pricing (Document LIO7860, Annex 2 to Advanz's response to question 1 of the CMA's s.26 notice dated 11 September 2019. Document LIO12043, Advanz RSSO-2020, paragraph 4.28).

[94] Separately, the DHSC stated that between 2011 and 2013 it discussed with Advanz the pricing of certain branded products. Those discussions were with the DHSC PPRS team, which had no remit in respect of the prices of unbranded products. Document LIO7865, Note of meeting between the DHSC and CMA dated 25 September 2019, paragraphs 10 and 11. There is a note of one such meeting, which took place on 25 July 2013 (Document LIO2393, Note of meeting between the DHSC and Advanz dated 25 July 2013). It says nothing about Advanz's generic portfolio or about its selling prices for generic drugs. Any adjustment to Advanz's portfolio that was discussed related exclusively to its branded drugs subject to the PPRS. The DHSC agreed to consider proposals for variations in the prices of those drugs. This meeting therefore had nothing to do with Advanz's prices for Liothyronine Tablets.

[95] Document LIO6288, Advanz RSO, paragraph 4.16.

[96] Document LIO2409, Email between the DHSC staff dated 3 July 2013.

Rather, it reflected the DHSC's assessment of the appropriate margin to allow community pharmacies across the board of Category M drugs.[97]

c. The absence of DHSC/NHS intervention cannot be said to amount to '*acquiescence*' to Advanz's prices or to create a legitimate expectation for Advanz

6.79 Advanz also argues that the DHSC/NHS was informed of Advanz's prices and decided not to exercise its powers to intervene. The DHSC/NHS must therefore be taken to have passively '*acquiesced*' to Advanz's prices, and this created '*a legitimate expectation for [Advanz] that its prices were acceptable*'.[98]

6.80 The absence of DHSC/NHS intervention should not be read as implying '*acquiescence*' to Advanz's prices, and the evidence shows that Advanz did not understand it in that way at the time.

6.81 As explained in sections 3.C.VI.b and 5.B.II.a of this Decision, the DHSC's policy during the Infringement Period was to rely on competition to control generic drug prices. Advanz was well aware of this. This is explained in Advanz's contemporaneous documents:

(a) '*Drugs not captured under the PPRS are not subject to formal price controls (with competition encouraged to ensure prices remain competitive)*'.[99]

(b) '*Un-branded product enjoys free pricing with an assumption that competitive dynamics will keep the prices down*'.[100]

6.82 On the assumption that competition would keep generic drug prices down, the DHSC therefore focused its limited resources on the area of most impact on its budget (in the context of prescribing: patented drugs). As explained above, Advanz's strategy was premised on the opportunities this presented where competition failed to work effectively. Again, this is explained in Advanz's contemporaneous documents. For example:

(a) The UK was '*well-penetrated by off-patent drugs, however disproportionate spend on on-patent drugs'*. As a result, '[o]*n-patent drug cost control will be focus for DoH with limited resources*'. '[T]*he key element for [Advanz] with its*

[97] See also Document LIO7865, Note of meeting between the DHSC and CMA dated 25 September 2019, paragraphs 28-29.
[98] Document LIO7781, Advanz RSSO-2019, paragraphs 1.6.8 and 5.34-5.77. Document LIO12043, Advanz RSSO-2020, paragraphs 1.20.2-1.20.3, 3.7, 3.36-3.39, 3.47, 3.68, 3.101, 3.147 and 4.64. See also document LIO6288, Advanz RSO, paragraphs 4.64 and 6.164; and document LIO6258, HgCapital RSO, paragraph 165.
[99] Document LIO0231, Advanz's '*Project Glacier Lenders Presentation_NOTES.pdf*', slides 10-17.
[100] Document LIO0232, Mercury Pharma materials presentation, September 2012, slide 10.

niche portfolio' was that whereas the DHSC's policy of relying on competition to control generic drug prices was effective *'on an aggregate basis', 'on an individual drug basis where there in [sic] no/little competition allows drug producers to increase prices … limited competitive pressures mean [Advanz] can drive price increases*'.[101]

(b) '*Approximately 40% of the generics market in the UK is unbranded. The pricing of these unbranded products is not regulated because competition suppresses pricing across the market as a whole. However, for smaller, niche formulations, the competitive forces may not work to suppress prices as efficiently as for larger volume products and create room for price growth*'.[102]

6.83 In this context, the absence of DHSC/NHS intervention in Advanz's prices cannot be said to amount to '*acquiescence*' to those prices. Nor can it have created a legitimate expectation for Advanz that its prices were '*acceptable*'. The Court of Justice has confirmed that:

> *'a person may not plead breach of the principle of the protection of legitimate expectations unless he has been given precise assurances by the competent authority'*.[103]

6.84 In this case no such assurances were provided (nor would the DHSC be the competent authority to give such assurances for the purposes of competition law).[104] Indeed, the DHSC has publicly stated that:

> *'If the Department has not engaged with a company about the price of its unbranded generic medicine this must under no circumstance be understood as approval of that price'*.[105]

6.85 Advanz's argument that the absence of DHSC/NHS intervention amounts to '*acquiescence*' is in any event premised on its claims that:

(a) The DHSC/NHS had sufficient information to make an informed decision not to intervene in its prices;[106] and

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[101] Document LIO0231, Advanz's '*Project Glacier Lenders Presentation_NOTES.pdf*', slides 10-16.
[102] Document LIO6490.3, *'Annex 2.1 - Minutes of a meeting of IC dated 2 July 2012'*, page 6.
[103] C-681/11 *Schenker*, paragraphs 40-41 and the cases cited. '*Precise assurances*' are those based on '*information which is precise, unconditional and consistent and comes from authorised and reliable sources*' (C-221/09 *AJD Tuna*, paragraph 72; see also C-545/11 *Agrargenossenschaft Neuzelle*, paragraph 25).
[104] Compare C-681/11 *Schenker*, paragraph 42; C-280/08 P *Deutsche Telekom v Commission*, paragraph 120, following the Opinion of the Advocate General (paragraph 34).
[105] Document PAD164, DHSC: '*Legal requirements to provide information about health service products*', June 2018, page 35.
[106] Document LIO7781, Advanz RSSO-2019, paragraphs 5.29-5.32.

(b) The DHSC/NHS could at any time have intervened in its prices, whether formally or informally.[107]

6.86 However:

(a) As explained above, the 'notifications' Advanz submitted to the NHS BSA and DHSC staff did not give the DHSC/NHS sufficient information to judge whether to 'accept' the price increases as reasonable or justified. In order to form that sort of judgement, in addition to a clear and mutually understood process for reviewing and assessing the prices of generic drugs (which it did not have), the DHSC would have needed much more detailed information about, for example, Advanz's costs relating to Liothyronine Tablets.

(b) As explained in section 4.C.IV.b (*The absence of countervailing buyer power*) of and Annex 5 to this Decision (*Dominance*), it is clear that the DHSC was not, as a matter of fact in this case, able to exercise buyer power in the form of regulatory power to influence Advanz's pricing.[108] Advanz was not effectively constrained by any meaningful prospect of the DHSC intervening in its prices of Liothyronine Tablets, whether under formal powers or informally.[109] As explained above, on the rare occasion that the DHSC did review Advanz's 'notifications', it noted that '*they have us over a barrel*'.[110]

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[107] Document LIO7781, Advanz RSSO-2019, paragraphs 5.39-5.77. Document LIO12043, Advanz RSSO-2020, paragraphs 1.20.2, 3.7.1, 3.36-3.39, 3.47, 3.68, 3.101, 3.147 and 4.64. See also document LIO12198, Advanz's representations on the 2021 Letter of Facts, paragraph 2.51.3.

[108] Compare *Phenytoin CAT* [2018] CAT 11, paragraph 207. Advanz submits that since the DHSC has not sought to exercise the new powers it obtained under the Costs Act on 7 August 2017 (after the Infringement Period ended), it must be taken to have acquiesced to prices charged during the Infringement Period (Document LIO7781, Advanz RSSO-2019, paragraph 5.77). However, as explained in section 3.C.VI.f of this Decision, while the Reserve Power has been available to the DHSC in relation to Liothyronine Tablets since 7 August 2017, it remains silent as to the method the DHSC should use to determine a price limit and the DHSC has yet to issue any public consultation on use of the Reserve Power. Supporting powers enabling the DHSC to impose financial penalties for non-compliance and to gather information to support the Reserve Power did not come into force until April and July 2018 respectively. As explained above, when responding to its consultation on those supporting information-gathering powers the DHSC expressly stated: '*If the Department has not engaged with a company about the price of its unbranded generic medicine this must under no circumstance be understood as approval of that price*'. Document PAD164, DHSC: '*Legal requirements to provide information about health service products*', June 2018, page 35.

[109] Advanz states that its 'pre-notifications' to the DHSC, discussed in section II.b.ii at paragraphs 6.65ff above, were submitted in the context of its 'group membership' of Scheme M, and that the DHSC could therefore have intervened using the provision in paragraph 30 of Scheme M if it did not acquiesce. Document LIO7781, Advanz RSSO-2019, paragraph 2.18; document LIO12043 Advanz RSSO-2020, paragraph 4.28. There is nothing on the face of Advanz's notifications to support the statement that they were made in the context of Scheme M. When the CMA put this to the DHSC it stated: '*[W]e are not aware of having requested this information under Scheme M and therefore the Department would not have used the data under the Scheme'* (Document LIO6878, the DHSC's response to question 2 of the CMA's s.26 notice dated 2 July 2018). In any event, as explained in section 4.C.IV.b *(The absence of countervailing buyer power*) of this Decision and Annex 5 (*Dominance*) above, even if Scheme M applied to Advanz's prices for Liothyronine Tablets this did not impose an effective constraint on those prices.

[110] Document LIO7893, Email between DHSC staff dated 3 June 2013.

III. Advanz's argument is wrong in law

a. Advanz's reading of *Genzyme* is wrong

6.87 Advanz argues that *Genzyme* establishes that, where a customer acquiesces to an undertaking's prices, that undertaking does not set those prices unilaterally.[111]

6.88 The CAT's findings on Genzyme's practice of bundling the price of homecare services with the price of its drug Cerezyme in the NHS list price of the drug should not be read as establishing any such principle.

6.89 When assessing this practice, the CAT began by noting that:

> *'the "bundling" together by a dominant undertaking, in one inclusive price, of separate but ancillary products or services may constitute an abuse where the effect is to eliminate or substantially weaken competition in the supply of those ancillary products or services'.*[112]

6.90 However, the CAT considered that '*closer analysis is required before one can draw the conclusion that it is sufficiently proved that the inclusion of Homecare Services within the NHS list price for Cerezyme was, in and of itself, necessarily an abuse in the period from March 2000 to May 2001*'.[113]

6.91 The CAT noted the following specific facts of the case:

(a) First, Genzyme's practice did not breach any NHS rules or practices, contrary to '*a central plank in the OFT's findings*';[114]

(b) Secondly, the OFT's case depended on the argument that, had the NHS wished to obtain healthcare services elsewhere, it would have had to '*pay twice over*' because Genzyme would not have been prepared to supply a competing provider of homecare services with Cerezyme at an unbundled price.[115] However, this was purely hypothetical and had not occurred in practice. There was no evidence that the NHS had wanted or sought an alternative provider of homecare services or proposed that Genzyme

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[111] Document LIO12043, Advanz RSSO-2020, paragraphs 1.20.3-4, 3.7.2, 3.8, 3.9, 3.11, 3.12, 3.15, 3.28, 3.33, 3.34, 3.48, 3.50 and 3.70. See also Document LIO6288, Advanz RSO, paragraph 4.23.3; Document LIO7781, Advanz RSSO-2019, paragraph 1.6.2.
[112] *Genzyme* [2004] CAT 4, paragraph 533.
[113] *Genzyme* [2004] CAT 4, paragraph 535.
[114] *Genzyme* [2004] CAT 4, paragraphs 536-537.
[115] *Genzyme* [2004] CAT 4, paragraphs 538-540.

'unbundle' its prices. The NHS had known about Genzyme's practice since it began many years ago and made no objection to it;[116] and

(c) Thirdly, the CAT was '*unpersuaded that there was … an obvious mechanism which Genzyme ought to have used to achieve the "unbundling" of Homecare Services*'. The only way for Genzyme to have been separately reimbursed for the drug and homecare services would have been through separate contracts with relevant hospitals or primary care trusts. However, there was no evidence that any hospital or trust had asked for such an arrangement. The CAT noted (specifically in relation to this point) that: '*Whatever the precise scope of the "special responsibility" of a dominant undertaking, we are reluctant to hold that Genzyme acted in breach of its special responsibility … when its only customer, the NHS, passively acquiesced in Genzyme's practice, and raised neither complaint nor criticism in that regard*'.[117] Moreover, Genzyme would have had to breach its agreement with Healthcare at Home to offer Cerezyme to other homecare services providers. In any event, there was no evidence that any other homecare services provider had sought to enter the market between March 2000 and May 2001, during which period '*the NHS displayed an essentially passive attitude*'.[118]

6.92 Overall, the CAT concluded that:

> *'In these circumstances we accept, in principle, the OFT's case … that, in the period between 1 March 2000 and 7 May 2001 Genzyme's practice of including the price of Homecare Services in the NHS list price for Cerezyme could have had the anti-competitive effect of preventing the NHS from using other homecare services providers …*
>
> *However, we doubt whether, in respect of <u>that</u> period, it is sufficiently proved that Genzyme's potentially anti-competitive conduct is to be characterised as an abuse for the purposes of the Chapter II prohibition, having regard to the facts that, during <u>that</u> period:*
>
> *there is no evidence that the NHS sought an alternative provider to Healthcare at Home, or that any other homecare services provider sought to obtain Cerezyme from Genzyme on discounted terms or otherwise;*

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[116] *Genzyme* [2004] CAT 4, paragraphs 541-542.
[117] *Genzyme* [2004] CAT 4, paragraph 543.
[118] *Genzyme* [2004] CAT 4, paragraphs 544-545.

the NHS knew of, and acquiesced in, Genzyme's practice of including Homecare Services in the NHS list price of Cerezyme;

it is not shown that Genzyme acted contrary to any aspect of the NHS system in including Homecare Services in the NHS list price for Cerezyme; and

it is not obvious how Genzyme would have been remunerated for the supply of Homecare Services had it "unbundled" the list price of Cerezyme, other than by virtue of a separate contract with the relevant hospital or PCT, but no body on behalf of the NHS ever sought or suggested any such separate contract.

In all these circumstances, the effect on competition of Genzyme's "bundling practice" in the period March 2000 to May 2001, although theoretically established, is not proved to have had a sufficient adverse effect on competition, in the particular circumstances of this case, to be characterised as an abuse'.[119]

6.93 The CAT's statements on NHS '*acquiescence*' in *Genzyme* were clearly (and expressly) confined to the specific facts of the case and the context of the abuse that the OFT had alleged: the exclusionary abuse of bundling, which on those facts was found not to have been proven. Since no competing providers of homecare services had sought to enter during the relevant period, and the NHS had not sought to obtain homecare services from anyone else or an unbundled price from Genzyme, Genzyme's bundling practice in itself had no negative effect on competition or on the NHS.

6.94 There is therefore no basis to read the CAT's statements on NHS '*acquiescence*' as establishing a legal principle that where a customer acquiesces to an undertaking's prices, there can be no abuse. The CAT did not find that these facts meant Genzyme's conduct was not unilateral: only that it was not proven to have had a sufficient adverse effect on competition. By contrast, Genzyme's conduct from May 2001 onwards, when Healthcare at Home and other providers were competing with Genzyme in the downstream market without making a margin, amounted to '*a clearcut abuse*' in that it was likely to have the effect of eliminating competition in the supply of homecare services.[120]

6.95 In any event, even if Advanz's reading of *Genzyme* were correct, the principle claimed by Advanz would not apply in this case. This case is very different

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[119] *Genzyme* [2004] CAT 4, paragraphs 546-548 (emphasis in original).
[120] *Genzyme* [2004] CAT 4, paragraphs 549-575 and 642.

from *Genzyme*. Whereas in *Genzyme* there was insufficient evidence of any effect on the NHS from Genzyme's bundling (indirectly through its being deprived of a choice of homecare services supplier), in this case there is ample evidence of the direct negative consequences of Advanz's prices for the NHS and patients (see section 5.E.III.e of this Decision).

b. Advanz's reading of *Genzyme* is inconsistent with subsequent caselaw

6.96 Advanz's reading of *Genzyme* is also inconsistent with subsequent caselaw.

6.97 In *Deutsche Telekom* – a case that postdates *Genzyme* – Deutsche Telekom's wholesale prices were set in advance by the German regulator, RegTP, on the basis of its assessment of the costs of efficient service provision. Deutsche Telekom's retail prices were subject to a cap across 'baskets'. In order to increase its retail prices within those baskets, it was required to apply to the regulator for advance permission (which was on one occasion refused). The General Court and Court of Justice rejected the argument that this degree of regulation meant the spread between Deutsche Telekom's wholesale and retail prices could not amount to an abusive margin squeeze. The Advocate General, whose Opinion the Court of Justice followed, stated:

> '*While the fact that RegTP did not oppose the appellant's abusive conduct may be regarded as inciting it in a way, the fact remains that, in and of itself, that does not exonerate the appellant from responsibility'.*[121]

6.98 The Court of Justice agreed, holding that the mere fact that Deutsche Telekom may have been encouraged by the intervention of the regulator to maintain its pricing practices could not prevent those practices from being abusive.[122]

6.99 By analogy, if prior approval of prices by a regulator does not absolve a dominant firm of its special responsibility not to abuse its position when setting those prices, the mere fact that a customer has paid a price without complaint cannot do so.

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[121] Opinion of AG Mazák, *Deutsche Telekom*, C-280/08P, EU:C:2010:212, paragraph 13. Compare *Albion Water II* [2008] CAT 31, paragraph 242: '*Even if the position of the regulator (in favour, at the material time, of access prices set according to regional average costs) and/or the relevant regulatory framework encouraged or made it easier for water companies to engage in anti-competitive conduct, those undertakings remained subject to the Act*'.

[122] *Deutsche Telekom*, C-280/08P, EU:C:2010:603, paragraph 84.

6.100 The case is also clear authority that the DHSC/NHS's failure to intervene using its 'regulatory' powers does not sanction Advanz's conduct. In the specific context of the DHSC's powers, the Court of Appeal has held:

> '*Case C-280/08 Deutsche Telekom v Commission confirms that the failure of the Department [the DHSC] to exercise any powers it may have had could not have absolved the appellants from their "special responsibility not to allow their conduct to impair genuine undistorted competition".'*[123]

6.101 *Deutsche Telekom* therefore shows that, if the presence of effective *ex ante* regulation does not exempt an undertaking from the law on abuse of dominance, an undertaking cannot claim that the absence of *ex post* 'regulatory' intervention does.[124] *Deutsche Telekom* is therefore relevant *a fortiori* to Advanz's case.[125]

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[123] Document PAD172, *Flynn Pharma Limited & Ors v Competition and Markets Authority*, Order made by the Rt. Hon. Lord Justice Newey, dated 12 December 2018.

[124] Nor can it create a legitimate expectation for the undertaking that its conduct complies with competition law: see Opinion of Advocate General Mazak in *Deutsche Telekom*, C-280/08P, EU:C:2010:212, paragraph 34; followed in paragraphs 21, 105-106 and 120 of *Deutsche Telekom*, C-280/08P, EU:C:2010:603. See also *Genzyme* [2004] CAT 4, paragraphs 613-614; and *Napp* [2002] CAT 1, paragraph 154.

[125] Advanz argues that *Deutsche Telekom* is irrelevant because it concerned the defence of '*state compulsion*', which allows for an undertaking accused of abusive conduct to prove that the regulatory framework in which it operates deprives it of all commercial autonomy, leaving it with no agency to abuse its dominance (Document LIO7781, Advanz RSSO-2019, paragraphs 4.7-4.9. Document LIO12043, Advanz RSSO-2020, paragraphs 3.65-3.69). It is correct that the case concerned state compulsion. However, that does not mean that *Deutsche Telekom* is irrelevant to Advanz's case for the reasons set out above.

Annex 6.3: The Unfair Limb – Economic value – other representations

6.102 Section 5.E.II.c of this Decision sets out the CMA's conclusion that none of the factors relied on by Advanz when setting the price of its Liothyronine Tablets were such as to provide '*benefits not reflected in the costs of supply*'[126] or '*any particular enhanced value from the customer's perspective*'.[127]

6.103 HgCapital argues that certain investments made during its ownership period were relevant to the economic value of Liothyronine Tablets.[128] The CMA accepts that certain investments referred to by HgCapital were made during the course of the Infringement Period. Although these were not specific to Liothyronine Tablets, they provided a wider benefit to Advanz's business, which included the supply of Liothyronine Tablets. Any investments that were relevant to Liothyronine Tablets are, however, already accounted for in the CMA's Cost Plus assessment. For example:

(a) Advanz invested in its supply chain by [✂] (see paragraph 3.177 of this Decision). However, [✂] has already been taken into account in the calculation of Cost Plus and is not of a material level.

(b) [✂]. However, [✂] is captured in the tangible fixed assets portion of capital employed in the Cost Plus calculation and again the scale of this investment is not material.

6.104 While investments in the wider business may have been made through expenditure of management time, for example in improving Advanz's relationship with the MHRA, and through recruitment of experienced staff, increasing salaries to improve staff retention and implementing training programmes to seek to professionalise the workforce, these are captured in the CMA's allocation of common costs (including staff costs) to Liothyronine Tablets.

6.105 Advanz also argues that the CMA should take account of the value provided by Advanz's supply of Liothyronine Tablets in ensuring access and continuity of supply of a niche medicine.[129] Relatedly, Cinven argues that Liothyronine Tablets are intrinsically difficult to manufacture and that *'a company which has "cracked" the manufacturing difficulty and can keep it stable over time has a significant competitive advantage over its actual or potential rivals, which it*

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[126] *Albion Water II* [2008] CAT 31, paragraph 7.
[127] *Albion Water II* [2008] CAT 31, paragraph 222.
[128] Document LIO6258, HgCapital RSO, paragraphs 13–38.
[129] Document LIO7781, Advanz RSSO-2019, paragraphs 8.128-8.129.

can reflect in a pricing premium'.[130] The CMA acknowledges that there is value in Advanz supplying Liothyronine Tablets. However, it considers that the economic value associated with doing this, including in relation to the complexity of production, is taken into account in the CMA's assessment of Advanz's costs (see section 5.D.II of this Decision).

[130] Document LIO7791, Cinven RSSO-2019, paragraphs 9.14-9.23.

Annex 6.4: The Unfair Limb – Unfair compared to competing products

6.106 Section 5.E.IV.a of this Decision sets out the CMA's conclusion that Post-Entry Prices may in principle provide a *prima facie* valid comparator or argument for the purpose of the second alternative of the Unfair Limb assessment, but that the prevailing Post-Entry Prices are not meaningful as a comparator as they remain contaminated by Advanz's abusive exercise of market power exerted over a decade. It also sets out the CMA's conclusion that Entry Plan Prices do not provide a *prima facie* valid comparator against which to assess whether the pricing of Liothyronine Tablets during the Alleged Infringement Period was fair.

6.107 This section sets out the Parties' detailed arguments in relation to Post-Entry Prices and Entry Plan Prices and responds to them.

I. Post-Entry Prices

a. New entry

6.108 Cinven submits that the fact that no new entry has occurred over the past three years is inconsistent with the CMA's provisional conclusion that current prices are excessive relative to the costs of production and entry.[131]

6.109 As a matter of fact, the CMA notes that two companies are still actively pursuing entry into the market for Liothyronine Tablets (see paragraph 3.110 of this Decision). This is consistent with the proposition that the current price is materially above any reasonable Cost Plus benchmark. In any event, even if new entry were not in prospect, it would not follow that the current price is at a competitive level.

b. The CMA's conclusion that prices continue to fall

6.110 Cinven makes a number of detailed representations on the CMA's conclusion that Post-Entry Prices continue to fall and remain contaminated by Advanz's exercise of market power during the Infringement Period.

6.111 First, Cinven submits that the ASPs presented in the 2020 SSO are blended averages across different distribution channels and do not reflect all rebates and distribution fees paid to wholesalers. As the magnitude of these discounts and rebates depends on the distribution model, and the mix between models

[131] Document LIO12055, Third Cinven CRA Report, paragraph 14.

fluctuates over time, average price data are not sufficient to make any meaningful inferences on trends over time.[132]

6.112 It is correct that ASPs do not incorporate certain rebates paid by manufacturers, but the effect of these rebates appears to be modest (see paragraph 5.301 of this Decision). Therefore, fluctuations in the mix of distribution models would have a limited impact on average prices and on observed price trends.

6.113 Second, Cinven submits that the detailed price data do not show a clear trend of falling prices, as prices differ between suppliers and have fluctuated from month to month.[133]

6.114 It is correct that ASPs in individual months will be affected by the operation of rebates and the lumpiness of spot transactions. However, the overall declining trend is clear. Moreover, as discussed in paragraph 5.315 of this Decision, it is not uncommon for generic price paths to exhibit temporary plateaus or even spikes before resuming decline. A short period of price stability cannot therefore be taken as evidence that the adjustment process has finished.

6.115 Third, Cinven submits that Teva's forecasts produced in the second quarter of 2020 [✂].[134]

6.116 The CMA notes that Teva's average prices [✂]. This is consistent with other information provided by Teva on its price forecasts for Liothyronine Tablets. While the document referred to by Cinven[135] shows [✂], in an interview on 3 June 2020, [✂], Director of Portfolio and Pricing for Teva UK, told the CMA that:

> '[✂]'.[136]

6.117 Fourth, Cinven submits that the CMA provides no evidence that prices will fall to the level predicted by its cost benchmark figure.[137]

6.118 The CMA does not consider it appropriate to seek to trace a price trajectory; this would be speculative and is unnecessary. However, the CMA concludes that the evidence is consistent with the proposition that Post-Entry Prices are likely to remain contaminated by the effect of dominance and abuse for a long

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[132] Document LIO12052 Cinven RSSO-2020,paragraph 5.44a.
[133] Document LIO12055, Third Cinven CRA Report, paragraph 28.
[134] Document LIO12055, Third Cinven CRA Report, paragraph 30.
[135] Document LIO11922, '*Teva Forecast Q2 2020*'.
[136] Document LIO11924, [✂] (Teva) interview transcript, page 27.
[137] Document LIO12055, Third Cinven CRA Report, paragraph 33.

period of time, and therefore are not a suitable comparator for the purpose of assessing the effectively competitive price of Liothyronine Tablets.

6.119 Fifth, Cinven points out that Oxera's report shows that the price of Category M drugs tends to drop to 10-20% of the price prevailing before loss of exclusivity. Applying this ratio to Liothyronine Tablets would imply prices stabilising around £25 to £50 per pack, which is much higher than the upper bound of the CMA's calculation of Cost Plus.[138]

6.120 The CMA considers that this would be an inappropriate basis for setting a benchmark for the purpose of deciding whether the prices charged by Advanz during the Infringement Period were fair. First, as a general point, it is illogical for the benchmark to depend on the price charged during the Infringement Period, as Cinven suggests. Second, the result from the Oxera report referred to by Cinven is based on an average trend observed across drugs, but significant variation exists between drugs. Long-term effectively competitive prices would depend on cost factors and competitive conditions and not on the price charged by the originator before the entry of rival suppliers. In other words, while prices are sticky (as discussed in paragraphs 5.311-5.319 of this Decision), they would not be affected by the originator's pre-entry prices indefinitely. As shown in Figure 5.15 of this Decision, the absolute price of Liothyronine Tablets upon entry was the highest among generic drugs in the Oxera sample. Therefore, in the case of Liothyronine Tablets, in the long term generic prices can be expected to drop to below the 10-20% observed on average across the drugs in the sample.

6.121 Sixth, Cinven submits that even if prices were to continue to decline and stabilise for some period at a lower level, the CMA's assumption that this lower level would be the new equilibrium is unfounded. For example, profits made during the period in which prices are falling may well be needed to sustain entry, i.e. prices may fall below cost.[139]

6.122 The CMA does not contend that only the lowest observed price can be considered as the long-term equilibrium price for a product. In some cases, certain additional contextual factors (such as the exit and/or re-entry of competitors) might be used in conjunction with price information to draw inferences about the competitive equilibrium. In the case of Liothyronine Tablets no competitor has exited the market since entry, two potential entrants are continuing efforts to enter the market, and prices have been on a broad downward trend since entry. These factors indicate that the process of

[138] Document LIO12055, Third Cinven CRA Report, paragraph 35.
[139] Document LIO12055, Third Cinven CRA Report, paragraph 36.

competition has not yet eliminated the impact of Advanz's abusively high prices during the Infringement Period.

c. Category M drugs as comparators

6.123 Cinven argues that Category M drugs are not a meaningful comparator for Liothyronine Tablets, as Liothyronine Tablets were in Category C and then Category A following entry until January 2019.[140]

6.124 The CMA refers to Category M drugs for two purposes:

(a) To compare the current price of Liothyronine Tablets to the typical prices of generic drugs. As Liothyronine Tablets have been in Category M since January 2019, using Category M drugs as comparators is appropriate.

(b) To show that the price stickiness that characterises Liothyronine Tablets is not uncommon among generic drugs. For this purpose, Category M drugs are used as examples. The CMA is not using this analysis to prove that the prices of Liothyronine Tablets are sticky (the actual price trend provides sufficient evidence of this), but only to show that this is not something unique to Liothyronine Tablets – rather it is a common feature of many generic drugs.

6.125 Advanz submits that the CMA has not explained why observations drawn from the entry of generic medicines into the market following the expiry of the originator's patent should apply to a situation where one or more generic drug firms have entered into the supply of Liothyronine Tablets in competition with an existing generic drug supplier.[141]

6.126 Unlike Liothyronine Tablets, a branded originator is present in the generics markets used in the Oxera samples. This means that the prices of generic drugs are constrained by the price of the branded drug, which in turn is typically regulated. This might have implications for the price level at which generic drugs are launched in the market: particularly in the presence of brand loyalty towards the originator, generic drugs may be introduced at a significant discount. However, the competition is subsequently overwhelmingly between generic providers, rather than between generic and branded versions of the drug. As Kanavos (2014)[142] reports, the prices of generic drugs in the UK continue to decline in the two years after generic entry, while the prices of originator brands are almost unaffected. The CMA, therefore, considers that the evidence on generic price dynamics for the drugs in the Oxera sample is informative of the evolution of generic prices that would be expected even for

[140] Document LIO12055, Third Cinven CRA Report, paragraph 21.
[141] Document LIO12043, Advanz RSSO-2020, paragraph 8.69.2.
[142] Kanavos, Panos (2014). Measuring performance in off-patent drug markets: a methodological framework and empirical evidence from twelve EU Member States. *Health Policy*, 118(2), 229-241.

drugs where a branded version is no longer supplied, as is the case for Liothyronine Tablets.

II. Entry Plan Prices

6.127 In response to the 2020 SSO, Advanz conducted a modelling exercise, which it submitted in support of the proposition that the DHSC would have been worse off if Advanz had been forced to charge prices for Liothyronine Tablets permanently below the level that attracted entry (the counterfactual scenario) than if Advanz had been allowed to charge prices that attracted entry (the factual scenario).[143] The CMA rejects this analysis, which relies on a number of assumptions that are unlikely to capture the likely trajectory of prices (in either the factual or counterfactual scenario).

6.128 First, Advanz assumes that in the counterfactual scenario (where Liothyronine Tablet prices are constrained by CMA intervention), prices would remain indefinitely at a level ranging from £45.66 to £247.87. The CMA considers that this assumption is not consistent with the principles set out in this Decision (or in the SSOs). The CMA has found that Advanz's prices from at least 1 January 2009 (when they rose to £20.48) were excessive and unfair and therefore infringed the Chapter II prohibition. In a scenario where Advanz had observed the principles set out in this Decision, it would not have indefinitely charged prices ranging from £45.66 to £247.87. The implication is that the costs incurred by the DHSC would have been significantly lower than those assumed by Advanz.

6.129 Secondly, Advanz assumes that in the factual scenario, prices converge to the CMA's estimate of incremental costs (£3.41) at some point between October 2020 and October 2022, and remain at that level indefinitely. The CMA considers that this assumption is not realistic. It is more reasonable to expect prices to fluctuate at a level close to (but typically exceeding) incremental costs. For example, if the initial price decrease triggers the exit of inefficient suppliers, this may in turn allow the remaining supplier(s) to temporarily raise the price.

6.130 These assumptions have a material impact on the results of the model and the conclusions that can be drawn from it. In fact, Advanz's own results show that the DHSC would have been better off in the counterfactual scenario even if regulatory intervention only involved capping prices at a level of £46.[144] By extension, the DHSC would have been ***significantly*** better off if Advanz had charged prices consistent with the principles set out in this Decision. As

[143] Document LIO7784, Second Compass Lexecon Report, section 5.
[144] Document LIO7784, Second Compass Lexecon Report, paragraph 5.18.

discussed in section 5.E.IV.b.iii (Entry Plan Prices) of this Decision, even if Advanz had charged the lowest price that the CMA has found to infringe the Chapter II prohibition (£20.48) from February 2009 onwards, the cost to the DHSC would have been at least £84 million ***lower***.[145]

[145] This calculation assumes that in the counterfactual scenario the price stays at £20.48 indefinitely. The factual price follows the real ASP from February 2009 to August 2018 and then gradually decreases to the incremental cost (£3.23). The real social discount rate is 3.5%, as in the Advanz's model.