Annex 3 – Costs plus a reasonable rate of return (Cost Plus)

3.1 This Annex sets out the detail behind the CMA's approach to calculating Advanz's Cost Plus. It further sets out a sensitivity analysis to Cost Plus in Section A3.F, '*Sensitivities to Cost Plus*'.

A. Advanz's costs

3.2 This section sets out the cost categories used; the information that Advanz supplied in respect of each of them; and the CMA's approach in calculating Cost Plus.

3.3 Table A3.1 below summarises the components of the Cost Plus calculation and the CMA's approach to estimating each component.

Table A3.1: Summary of CMA's overall approach to the Cost Plus calculation

Category	Explanation of cost	CMA's approach
Direct costs	Costs directly attributed to the supply of Liothyronine Tablets in the UK.	Include all direct costs that are relevant to the supply of Liothyronine Tablets, based on data provided by Advanz.
Indirect costs	Common costs which are shared across multiple products, including Liothyronine Tablets, such as corporate overheads.	Allocate common costs using an output-based cost driver: sales volumes (number of packs sold). Sensitivity analysis using an adjusted version of Advanz's activity-based costing model.
Reasonable rate of return: capital employed	Value of the tangible and intangible assets and working capital – deducting depreciation and amortisation.	Product Rights are not amortised during the Infringement Period. Depreciation of shared fixed assets follows Advanz's accounting approach and is allocated using pack volumes. Sensitivity analysis for different amortisation profiles on Product Rights.
Reasonable rate of return: Cost of capital	Return to investors – captured by multiplying the weighted average cost of capital (WACC) by the capital employed.	Capital employed is estimated using the value to the business framework. A 10% WACC is multiplied by the capital employed. Sensitivity analysis is undertaken for a 15% WACC and different Product Rights valuations.

Source: CMA analysis.

3.4 The CMA's Cost Plus (i.e. the 'costs actually incurred' in supplying Liothyronine Tablets, including both direct and indirect costs together with a reasonable rate of return) during the Infringement Period ranged from £1.95-2.10 to £9.65-9.90. This can be compared with annual ASPs of £20.80 to £247.77 over the same period.[1]

3.5 As a cross-check to the CMA's Cost Plus, a sensitivity analysis is carried out with respect to:

(a) Allocation of common costs – an adjusted version of Advanz's activity-based costing analysis to the CMA's output-based cost driver;[2]

(b) Valuation of Product Rights – to test the impact of applying a risk of failure adjustment to the Product Rights valuation and different amortisation profiles of the Product Rights;[3] and

(c) Required rate of return – a higher rate of return, i.e. a WACC of 15% (applied to Advanz's capital employed except in relation to working capital).[4]

3.6 The cumulative application of the sensitivities increases the CMA's Cost Plus, on average, by £2.41 or 49%.[5]

I. CMA's approach to the analysis of costs

3.7 This section describes the CMA's approach to analysing cost information provided by Advanz and third parties, in order to calculate Cost Plus and the sensitivities applied by the CMA in response to the Parties' representations.

3.8 The three main areas where the CMA has adjusted the data provided by Advanz are:

(a) Where the cost data provided by Advanz were incomplete or unreliable, the CMA has had to make assumptions or extrapolations based on the information that was provided to obtain a complete set of cost information (see paragraphs 3.11 to 3.13 ('*Dealing with incomplete and unreliable data*') below);

[1] £20.80 is the lowest annual ASP; the lowest monthly ASP was £20.48 in January 2009 and the highest monthly ASP was £247.87 in July 2017.
[2] The CMA's sensitivity on common cost allocation increases Cost Plus, on average, by £0.68 per pack, from £0.62 to £1.30 per pack.
[3] The CMA's sensitivity on Product Rights increases the Product Rights valuation from [✂] to £2.1 million, which in turn increases Cost Plus, on average, by [✂] per pack, from [✂] to £1.84 per pack.
[4] The CMA's sensitivity on WACC (15%) increases the reasonable rate of return required per pack, on average. by [✂] per pack, from [✂] to [✂] per pack.
[5] The CMA's average Cost Plus increases by £2.41 per pack, from £4.94 to £7.35 per pack once the sensitivities are applied cumulatively.

(b) To allocate common costs on an appropriate basis (see section A3.C ('*Indirect costs*') below); and

(c) Where the acquisition or historical costs of an asset are materially below what it would cost today to purchase or replicate that asset, the CMA has estimated asset value(s) using the *'replacement cost*' (see section A3.D ('*Reasonable rate of return*') below), as this is likely to better reflect the true economic cost of the asset.

3.9 The CMA's approach to assessing the value of the Product Rights (Advanz's most material asset used in the supply of Liothyronine Tablets), the approach to common cost allocation and the appropriate rate of return on capital are the main areas of judgement within Cost Plus and represent the main areas of difference between the CMA and the Parties with respect to the calculation of Cost Plus.

3.10 In response to the Parties' representations, the CMA has applied a series of sensitivities to the data used in its Cost Plus analysis to assess the effect of using alternative methods in these areas in Section A3.F, '*Sensitivities to Cost Plus*'. These sensitivities serve as cross-checks to the results obtained.

II. Dealing with incomplete and unreliable data

3.11 Advanz informed the CMA that its business accounting information relating to Liothyronine Tablets has only been consolidated in one accounting system since January 2014 (an SAP system – data for Amdipharm previously came from a different accounting system). Advanz told the CMA that the management accounts in the pre-January 2014 period were less comprehensive than from 2014 onwards.[6]

3.12 The first main area where assumptions are required in the analysis relates to the estimation of indirect costs in the pre-2014 period. The CMA has used the average costs from the 2014 to 2017 cost data for the remainder of the Infringement Period, i.e. 2009 to 2013. This assumes that indirect costs pre-2014 were consistent with indirect costs between 2014 and 2017.[7] In the CMA's view, this is an appropriate approach, given the data available because:

[6] Document LIO1901.1, Note of call between the CMA and Advanz, dated 19 January 2017.

[7] This assumption holds for the cost allocation approach used in Cost Plus, where the average indirect costs for 2014-2017 are allocated on the basis of volumes. However, where the CMA runs a sensitivity analysis for ABC, the equi-proportional mark-up ('**EPMU**') driver is calculated by taking the costs already allocated to Liothyronine Tablets as a proportion of total costs available for allocation. Where the total costs available for allocation are the actual direct costs for the year in question plus the average indirect costs for 2014-2017, this approach results in a higher EPMU driver in the earlier period, when the business was smaller. This is because total direct costs were smaller, so the costs already allocated to Liothyronine Tablets as a proportion of total costs available for allocation is greater.

(a) In response to the 2017 SO, Advanz submitted that approximately 50% of the indirect cost data provided for the Infringement Period were unrelated to Liothyronine Tablets.[8] However, Advanz was only able to extract the costs unrelated to Liothyronine Tablets from the 2014 to 2017 data, given the limitations of its pre-2014 data.[9]

(b) Advanz submitted that the pre-2014 data were less comprehensive, as described at paragraph 3.34 below.

(c) Advanz's data for group level indirect costs increased during the Infringement Period and therefore the CMA considers that the assumption that the indirect costs in 2014 to 2017 applied throughout the pre-2014 period is favourable to Advanz.[10,11]

3.13 Secondly, the CMA's analysis has been carried out on an annual basis. The CMA asked Advanz to provide monthly asset data, but Advanz said that this would be difficult and offered to provide asset data as at the end of each accounting period.[12] The CMA accepted this as a proportionate approach.

B. Direct costs

3.14 Direct costs are those costs that are directly attributable to the supply of Liothyronine Tablets in the UK. Advanz provided information in respect of the following direct costs throughout the Infringement Period:[13]

(a) The cost of purchasing Liothyronine Tablets from [✂], its Contract Manufacturing Organisation (CMO);

(b) Fees paid to [✂] in respect of technical expert support in relation to the manufacture of Liothyronine Tablets;

(c) Dual sourcing costs;

(d) Stock write-off costs; and

[8] Document LIO6361.3, First FTI Report, paragraph 8.22 and Table 8-2.
[9] Document LIO6361.3, First FTI Report, paragraph 8.20.
[10] See for example, document LIO6664, Advanz's response to question 3 of the CMA's s.26 notice dated 7 June 2018. Advanz stated that costs were lower prior to 2012.
[11] The approach of assuming constant indirect costs (in monetary terms) does not appear reasonable when estimating depreciation as the data show that capital costs varied over the Infringement Period. The CMA has therefore allocated depreciation costs on the basis of pack volumes throughout the Infringement Period. The approach taken to depreciation is not material to the overall assessment.
[12] Document LIO1901.1, note of call between the CMA and Concordia on 19 January 2017.
[13] Direct costs of production throughout the Infringement Period were provided in document LIO4426, Advanz's response to the CMA's s.26 notice dated 6 September 2017. These direct cost figures did not include one-off costs associated with dual sourcing, stock write-offs and BSV costs.

(e) Batch specific variation (BSV) costs.[14]

3.15 The costs of purchasing Liothyronine Tablets are the direct costs of production and relate to the fees paid to [✂] for the manufacture of Liothyronine Tablets. These costs are low (between [✂] and [✂] per pack) and have remained stable throughout the Infringement Period. The dual sourcing, stock write-off and BSV costs are one-off costs that were not incurred evenly throughout the Infringement Period. Specifically, the dual sourcing costs relate to Advanz's activities to identify alternative CMOs in an attempt to gain continuity of supply of Liothyronine Tablets. Stock write-off costs are the costs associated with the destruction of stock purchased from [✂] that was not sold or was returned by the wholesaler. BSV costs relate to additional testing or adjustments that Advanz has had to undertake to meet regulatory requirements (see paragraphs 3.19 to 3.24 below for more detail).

3.16 Marketing, storage and distribution costs would commonly be considered as direct costs as the costs are directly attributable to the supply of Liothyronine Tablets. However, as Advanz reports these costs at a group level rather than recording them as direct costs for individual drugs, these costs are accounted for in the CMA's Cost Plus as an 'indirect cost', i.e. a proportion of the group level costs are allocated to Liothyronine Tablets, on the same basis as other 'indirect costs'.

3.17 Product Rights are directly attributable to the supply of Liothyronine Tablets. The CMA recognises Product Rights as an intangible asset and includes the asset as an attributable asset in Advanz's capital base. The relevant input to the Cost Plus assessment is the opportunity cost of holding the Product Rights assets during the Infringement Period. This is accounted for in the reasonable rate of return category, i.e. the 'Plus'[15,16] (see paragraphs 3.92 to 3.122 below for more detail).

3.18 The amortisation charges relating to Product Rights are recognised as a direct cost.[17] As explained in paragraph 3.152 below, for the purposes of Cost Plus, the CMA does not amortise Product Rights and no amortisation is charged. As a sensitivity to the CMA's Cost Plus, the CMA amortises the sensitised Product

[14] Dual sourcing and stock write-off costs were provided as part of the Advanz RSO (document LIO6288). See document LIO6284.60, *'FTI Report Evidence Item-17 -* [✂] *Data_01032018.xlsx'*; document LIO6284.61, '*FTI Report Evidence Item-18 - Piramal POs'*; and document LIO6284.72, *'FTI Report Evidence Item-29 - Stock write off - Liothyronine tabs - 2010-2017'*.

[15] The CMA's approach to estimating the value of Product Rights is set out in section A3.D ('*Reasonable rate of return*') below.

[16] The reasonable rate of return – the 'Plus – is determined by applying the WACC to Advanz's capital base.

[17] The amortisation of Product Rights is only relevant in the CMA's sensitivity analysis. In the CMA's Cost Plus, Product Rights are assumed to hold a constant value and are not amortised.

Rights valuation over 20 years and an amortisation charge is recognised as a 'direct cost'.

I. BSV costs

3.19 In response to the 2019 SSO, Advanz reviewed some of its financial data for the period 2014 to 2017 and identified that [✂] of costs accounted for in the 'Technical, regulatory and specific' cost category related to 'additional stability tests' for Liothyronine Tablets.[18] Advanz submits that these costs related to the additional validation and testing required to ensure that each batch of Liothyronine Tablets produced is safe and meets the MHRA guidelines.[19] The additional validation and testing is due to the MHRA's requirement that Advanz produces Liothyronine Tablets in accordance with a formula (originally developed by Glaxo in the 1950s) that involves the use of particular manufacturing techniques. Because of this requirement, Advanz needs BSVs to be approved by the MHRA for each batch of Liothyronine Tablets that is produced.

3.20 The CMA asked Advanz to provide supporting evidence to verify the nature and timing of the costs incurred. Advanz was only able to provide evidence to support [✂] of the [✂].[20] Of those verifiable costs, the CMA identified a further [✂] of costs that it decided should be excluded from the analysis, as these costs related to services provided after the end of the Infringement Period.[21] As a result, in the CMA's view, only [✂] of the [✂] are relevant to Liothyronine Tablets and have been included in the CMA's Cost Plus assessment.

3.21 The activities accounted for in the 'Technical, regulatory and specific' cost category are group level costs that relate to Advanz's portfolio of drugs including Liothyronine Tablets. Advanz submits that the identification of Liothyronine Tablet-specific costs within this category supports an argument that a higher proportion of these group level costs should be allocated to Liothyronine Tablets than to Advanz's other drugs.

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[18] Document LIO7790.5, '*FTI Report Evidence Item-47 - BSV costs 2014 - 2017.ods*'.

[19] Document LIO7832, Advanz's response to the CMA's s.26 notice dated 29 July 2019, page 1. Advanz submits that the additional stability testing costs are different in nature to both the payments made to [✂] for volumes of Liothyronine Tablets and the stock write-off costs. Advanz also submits that these costs are distinct from the Liothyronine Tablet dual sourcing costs and were not double-counted elsewhere in the Cost Plus assessment.

[20] See document LIO7832, Advanz's response to question 2 of the CMA's s.26 notice dated 29 July 2019; document LIO7833, '*Confidential Annex 1 -- Update to Evidence Item 47 - 20 August 2019*'; document LIO7834, '*Confidential Annex 2 -- Invoices - BSV and additional dual sourcing - 1. BSV costs - POs and invoices*'; document LIO7835, '*Confidential Annex 2 -- Invoices - BSV and additional dual sourcing - 2. Additional dual sourcing - POs and invoices*'.

[21] See document LIO7851, '*RE_ Case 50395_ CMA request for information*'; document LIO7853, '*RE_ Case 50395_ CMA request for information*'; document LIO7854, '*Amdipharm Liothyronine invoice details CMA Sep 2019*'.

3.22 Based on the evidence submitted by Advanz, the CMA considers that instead of allocating a higher proportion of the group level costs to Liothyronine Tablets (i.e. as an indirect cost), it would be more appropriate to treat the relevant BSV costs as a direct cost for the following reasons:

(a) The identified BSV costs are directly attributable to Liothyronine Tablets and therefore, based on the principle of cost causality, the CMA recognises those costs as direct costs, in the year the costs were incurred.

(b) Under the CMA's approach, all identified BSV costs are recognised in full in the year the activity took place in both its Cost Plus and its sensitised Cost Plus assessment. Conversely, Advanz's approach of applying a general percentage driver to the 'Technical, regulatory and specific' cost category would allocate BSV costs to each year of the Infringement Period, including those years when no BSV-related activity took place.

(c) Advanz has not undertaken an exercise to identify whether the remaining costs in the 'Technical, regulatory and specific' cost category relate to activities that are directly attributable to other drugs. Without any such adjustment, allocating a general percentage driver to costs, some of which may well relate exclusively to other drugs, will likely lead to an overstatement of costs attributable to Liothyronine Tablets.

3.23 The CMA notes that the BSV-related activities and associated costs appear to be one-off costs and were not evenly incurred during the Infringement Period. The CMA has treated the BSV costs identified by Advanz as specific to Liothyronine Tablets and assumed that they were efficiently incurred.[22] The CMA recognises all of the actual BSV costs in the year incurred (i.e. in each year between 2014 and 2017).

3.24 Advanz submits that it also undertook BSV activity in 2011 and 2013, but was unable to provide an estimate of these costs. Advanz submits that most of its BSV-related activity in 2011 and 2013 was carried out internally and only 9. [✂] of any costs incurred were paid to [✂]. Although the nature of the activity in 2011 and 2013 appears to be different from the activity carried out in the period from 2014–2017, as most of it was carried out internally rather than externally (as explained at paragraph 3.23 above, the BSV costs relate to one-off activities) the CMA has nonetheless applied an average of the costs incurred during the period 2014 to 2017 to the two years for which no cost information was provided by Advanz, i.e. 2011 and 2013.

[22] It is possible that some of the dual-sourcing, stock write-offs and BSV costs may, in fact, have been inefficiently incurred. However, the CMA does not have sufficient information to assess this. The CMA's assumption that these costs were reasonably and efficiently incurred is favourable to Advanz.

II. Conclusion regarding direct costs based on the CMA's analysis of Advanz's costs

3.25 The direct cost contribution to the CMA's Cost Plus assessment is set out in Table A3.2 below.

Table A3.2: Direct costs based on the CMA's analysis of Advanz's costs

	2009	2010	2011	2012	2013	2014	2015	2016	2017
Total direct costs £000s	50	50	177	83	226	213	212	619	242
Cost of purchase per pack £s	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Dual sourcing/stock write-offs per pack £s	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
BSV costs per pack £s	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Total direct costs £s	**0.35**	**0.35**	**1.17**	**0.58**	**1.49**	**1.44**	**1.42**	**4.01**	**3.23**

Source: CMA Cost Plus assessment – 'Direct costs plus one-offs', 'Direct costs plus BSV' and 'Cost stacks post reps' tabs

C. Indirect costs

3.26 In addition to the direct purchase cost of the drugs it supplies, Advanz also incurs costs that are not directly related to the supply of individual products or product groups. These are 'indirect costs'. A proportion of indirect costs may be allocated to the different products that a firm produces or supplies.

3.27 Common costs are allocated between all the products supplied by Advanz. Accordingly, it is necessary to determine the share that it is appropriate to include in the Cost Plus assessment for Liothyronine Tablets. There are three broad types of cost drivers that can be used separately or in combination. These are: (i) output-based cost drivers; (ii) input-based cost drivers; and (iii) value-based cost drivers[23]

3.28 The CMA concludes that using **output-based cost drivers**, where indirect costs are allocated using output indicators such as production or sales volumes, is the most appropriate way to allocate common costs in this case. More specifically, the CMA has used sales volumes (number of packs sold) as the output-based driver in this case.

[23] A cost driver is a measure of an activity which either causes a particular cost or which might be considered to be closely correlated to the cost.

3.29 However, the CMA recognises that there is no single valid approach to common cost allocation and that alternative methods may also be appropriate, where the information required is both available and reliable. In response to representations from the Parties and as a cross-check to the output-based (volume) cost driver, the CMA has carried out a sensitivity assessment using an input-based cost driver, based on an adjusted version of Advanz's activity-based costing model.

I. Common and joint costs

3.30 Indirect costs may include:

(a) Costs which are common across a number of products; and

(b) Joint costs which arise when two or more products are necessarily purchased or produced together.

3.31 Common costs are those incurred in the supply of more than one product.[24] Typically they include costs relating to, for example, employees dealing with administrative matters (e.g. finance and legal departments) and head office overheads (e.g. utilities, rent and rates). To determine an appropriate allocation of common costs for a particular product, a proportion of total attributable common costs can be allocated to each of the products that a company supplies.

3.32 Advanz did not have any joint costs in relation to Liothyronine Tablets.[25] Accordingly, only common costs are relevant to the assessment of the level of indirect costs incurred by Advanz in supplying Liothyronine Tablets in the UK. Depreciation of group tangible fixed assets is also treated as an 'indirect cost', as these assets are shared across all drugs in Advanz's portfolio.[26]

3.33 Advanz has provided the CMA with information on the total common costs incurred at a group level between 2014 and 2017.[27]

3.34 Advanz has also provided some data on indirect costs prior to 2014. These include monthly indirect cost data throughout the Infringement Period relating to the cost of transporting, cost of sales and marketing and general and administrative expenditure.[28] The data were extracted from a number of

[24] In this case, Advanz incurs costs related to the supply of all medicines that it sells into the UK. These include, but are not limited to, Liothyronine Tablets.
[25] Document LIO2944, Advanz's response to question 17 of the CMA's s.26 notice dated 26 May 2017.
[26] See paragraph 3.155 below.
[27] Document LIO6284.82, FTI Report '*Evidence Item 40 – My Model*', Indirect cost tabs.
[28] Document LIO4426, Advanz's response to the CMA's s.26 notice dated 6 September 2017.

different historical accounting systems.[29] Advanz submits that these data include costs that were not associated with the supply of Liothyronine Tablets in the UK such as costs specific to other countries.[30] Advanz submits that approximately 50% of the indirect costs provided are unrelated to Liothyronine Tablets.[31] Based on this information, it has not been possible reliably to determine the indirect costs incurred by Advanz before 2014.

3.35 In the absence of good quality information on indirect costs prior to 2014, the CMA has applied the average 2014-2017 costs over the remainder of the Infringement Period. This assumes that indirect costs pre-2014 were consistent with indirect costs between 2014 and 2017. In the CMA's judgement, this is a reasonable approach, given the issues with Advanz's pre-2014 cost data but, as explained in paragraph 3.12(c) above, this approach is likely to be favourable to the Parties.

II. Cost drivers to allocate common costs

3.36 In relation to common costs, as noted in a 2003 discussion paper prepared for the OFT by Oxera titled '*Assessing profitability in competition policy analysis*' (the '**Profitability Assessment Report**'), there is no single correct method for cost allocation but various different methods may be appropriate, depending on the circumstances.[32] The Profitability Assessment Report identifies three broad types of cost drivers that can be used separately or in combination. These are:

(a) **Output-based cost drivers**, where indirect costs are allocated using output indicators, such as production or sales volumes;

(b) **Input-based cost drivers**, where indirect costs are allocated to a particular line of business based on other known inputs employed in the production of that line of business, such as labour employed, raw-material, costs of floor space used; and

(c) **Value-based cost drivers**, where indirect costs are allocated based on demand factors, such as prices, revenues or consumers' willingness to pay.[33]

[29] See Annex 6 to the 2019 SSO for further detail of the information systems from which each piece of data was drawn.
[30] Document LIO6361.3, First FTI Report, paragraph 8.22 and Table 8-2.
[31] Document LIO6361.3, First FTI Report, Table 8-2. Costs unrelated to Liothyronine Tablets of c.£35 to £39 million compared to c.£73 to £79 million total indirect costs.
[32] OFT657, '*Assessing profitability in competition policy analysis'*, Economic discussion paper 6, July 2003, prepared by Oxera, paragraph 6.15.
[33] *Profitability Assessment Report*, paragraph 6.16.

3.37 The Inter-Regulatory Working Group[34] identified four principles upon which cost allocation approaches should be based.[35] Of these, the CMA concludes that the following principles are most relevant in the context of this case and should therefore be taken into account when seeking to identify an appropriate cost allocation methodology:[36]

(a) ***Objectivity*** – Costs should be allocated on an objective basis, not unduly benefiting any particular party.

(b) ***Transparency*** – The method should be clear to all interested parties with the underlying data (costs, revenues, asset values, etc.) all being clearly identifiable.

(c) ***Cost causality*** – Costs should be allocated in accordance with the activities that cause them.

a. Output-based cost drivers

3.38 Output-based cost drivers, such as a volume-based approach, are a recognised approach to allocating common costs.

3.39 Based on the principles set out in paragraph 3.37 above, and the available evidence, the CMA concludes that using an output-based cost driver is the most appropriate method to allocate common costs to Liothyronine Tablets in this case because:

(a) It is transparent and practical to allocate common costs using output-based cost drivers since data on the number of packs sold are readily available.

(b) Using volume (number of packs sold) to allocate common costs ensures that the cost allocation is objective. If the cost allocation exercise is undertaken across the whole portfolio (i.e. calculating the proportion of Liothyronine Tablet sales volumes relative to all of Advanz's sales volumes), total common costs are recovered and no more.

[34] The Inter-Regulatory Working Group was established to identify and develop areas of consistency within published regulatory accounts.

[35] These principles are described in a paper from the Inter-Regulatory Working Group (2001), *'The Role of Regulatory Accounts in Regulated Industries: A Final Proposals Paper'* by the Chief Executive of Ofgem, Director General of Telecommunications, Director General of Water Services, Director General of Electricity and Gas Supply (Northern Ireland), Rail Regulator, Civil Aviation Authority, and Postal Services Commission.

[36] The other criterion identified by the inter-regulatory working group, in the *Profitability Assessment Report*, is *'consistency'*. This is less relevant in the context of this case as it relates more specifically to its application in regulatory accounts where it is important to ensure the same method is used from year to year.

b. Input-based cost drivers

3.40 Input-based cost drivers, which allocate a company's indirect costs using a cause and effect cost driver approach, can also provide a suitable and effective method of allocating common costs to individual products and services when applied correctly. This is consistent with the cost causality principle.[37]

3.41 An example of this approach is activity-based costing. The CMA considers that an activity-based costing approach to common cost allocation can be appropriate, where suitable information is both available and reliable.

3.42 In response to the 2017 SO, Advanz provided an activity-based costing model, using the 2014 to 2017 indirect cost data, to allocate Advanz's common costs to Liothyronine Tablets.[38,39] Advanz does not, however, use activity-based costing as part of its normal course of business. Given the limitations of Advanz's cost data, the choice of allocation and percentage drivers used in Advanz's model were based on management assumptions that were not supported by sufficiently robust, independent and reliable data. As a result, the CMA considers that Advanz's activity-based costing assessment was neither sufficiently objective nor transparent.

3.43 Therefore, in this case, the CMA concludes that activity-based costing is not a suitable and reliable way of allocating common costs to Liothyronine Tablets.

3.44 While the CMA has not carried out an activity-based costing approach in its Cost Plus calculation, it has nonetheless carried out a sensitivity analysis using an adjusted version of Advanz's activity-based costing model as a cross-check (see paragraphs 3.172 to 3.186 below).

c. Value-based cost drivers

3.45 The CMA has also considered value-based cost drivers. Value-based cost drivers can be a transparent and practical way to allocate indirect costs. However, the use of value-based cost drivers can sometimes result in allocations which fail to be objective. This means they are often considered inadequate for the assessment of pricing abuses under competition law.

3.46 For example, sales revenues are an example of a value-based cost driver. By using sales revenues, a greater proportion of indirect costs would be allocated to higher priced products, which is circular when assessing whether prices are

[37] For example, if electricity charges vary according to the length of time machines operate, then equipment hours per product will be an appropriate basis for apportioning these costs.
[38] Document LIO6361.3, First FTI Report, paragraph 8.20.
[39] Activity Based Costing is a costing method that allocates common costs on the basis of the causal links between the costs incurred by the business and the activities driving those costs.

excessive. This is because an excessive price attracts a disproportionate share of common costs, reducing the observed profitability of the product and potentially 'hiding' the excessiveness.

3.47 These problems were recognised by the CAT in *Genzyme* where it confirmed that the OFT was right to reject '*Healthcare at Home's submission that certain costs should be allocated solely according to turnover: such an approach would allocate an unduly high proportion of overheads to Genzyme, because of the high cost of the drug'*.[40] The same issue was also noted by the CAT in *Socrates v. Law Society* where the CAT noted that '*the method of cost allocation (whereby an increase in revenue automatically generates a corresponding increase in attributable cost) [is] an unreliable basis for any fair assessment of the profitability of the scheme*.'[41,42]

3.48 For these reasons, the CMA has rejected using a value-based cost driver, such as sales revenue, as a potential cost allocation methodology for the purposes of its analysis.

III. Conclusions regarding indirect costs based on the CMA's analysis of Advanz's costs

a. Common costs

3.49 As set out at paragraphs 3.38 and 3.39 above, as part of its Cost Plus calculation, the CMA has allocated common costs using volume (number of packs sold). Advanz provided the CMA with cost data that showed that, on average, between 2014 and 2017, Advanz's annual group level indirect costs were approximately £37.4 million.[43] The CMA allocates a proportion of these group level indirect costs to Liothyronine Tablets as an 'indirect cost' for the purposes of its Cost Plus assessment.

3.50 The CMA has allocated these costs using Liothyronine Tablets sales volumes (number of packs sold) as a percentage of Advanz's global pack volumes, which was between 0.18% and 0.23%.[44]

3.51 The CMA considers that it is appropriate to use Liothyronine Tablets pack volumes as a proportion of global pack volumes because the common cost figures to which the driver is applied largely relate to Advanz's global

[40] *Genzyme Remedy* [2005] CAT 32, paragraph 268.
[41] *Socrates v Law Society* [2017] CAT 10, paragraph 83.
[42] The issues with revenue-based allocation were also recognised by the CAT in *Phenytoin CAT*. See *Phenytoin* [2018] CAT 11, paragraphs 351 to 352.
[43] CMA Cost Plus assessment – 'Indirect cost allocation' tab.
[44] CMA analysis of Advanz data. This is consistent with Advanz's own submissions on the volume driver – see for example, document LIO6284.82, '*FTI Report Evidence Item-40 - My Model*' – *'Indirect costs'* tabs.

operations.[45] The exception are those costs which have been reported as UK-specific costs. The CMA accepts that an allocation driver based on global volumes may understate the portion of the UK-specific costs allocated to Liothyronine Tablets. However, the CMA has also undertaken a sensitivity analysis using different allocation drivers (see paragraphs 3.172 to 3.186 below).

b. Expert support costs

3.52 Advanz submits that '*[f]rom November 2013 to October 2014, Advanz supported* [✂] *with* [✂] *per month (which totalled* [✂]*). These amounts were accounted as fees paid for expert support with key products and thus were not repaid by* [✂]*. However, the intention was to provide improved cash flow to* [✂]'.[46]

3.53 Advanz submits that the purchase orders covered activities such as '*general expert support allowing* [✂] *to provide process improvement activity, investigations, etc.'* and that *'[a] secondary purpose of this exercise was to provide* [✂] *with a regular additional guaranteed revenue stream*.'[47] Advanz states that its actions '*provided the financial stability and security that* [✂] *needed in order to resolve its financial difficulties*'.[48]

3.54 The [✂] payment was therefore intended to allow [✂] to provide ongoing support activities and was also intended to act as an additional source of revenue for [✂]. The timing of the payments to [✂] was not directly related to the performance of the services nor to the period of time that the additional source of revenue was meant to cover.

3.55 The CMA has allowed one fifteenth of the [✂] support costs to be included in the Cost Plus assessment for Liothyronine Tablets. This reflects the fact that [✂] manufactured 15 different products for Advanz[49] and the support payments will have benefitted Advanz in respect of each product.[50]

[45] This is consistent with the volume driver used by Advanz. See document LIO6361.3, First FTI Report, paragraph 8.33(3).
[46] Document LIO1521, Advanz's response to question 7 of the follow-up questions to the CMA's s.26 notice dated 25 October 2016.
[47] Document LIO2553, Advanz's response to outstanding items after the call with the CMA held on 9 February 2017.
[48] Document LIO1521, Advanz's response to question 7 of the follow-up questions to the CMA's s.26 notice dated 25 October 2016.
[49] Document LIO1526, *'Draft Finance Review on* [✂] *– May 2013'*, page 24.
[50] The Parties did not propose a different approach to these costs in their representations.

3.56 Expert support costs are recognised in the periods during which they were incurred.[51] The result is an additional [✂] and [✂] of indirect costs per pack in 2013 and 2014, respectively.[52]

c. Depreciation

3.57 In respect of depreciation of shared tangible fixed assets, the CMA obtained data from Advanz which included depreciation by accounting period and by asset category.[53] Depreciation of group fixed assets is a common cost, which is shared across all drugs in Advanz's portfolio.

3.58 As set out in paragraph 3.39 above, the CMA has allocated all common costs between Liothyronine Tablets and Advanz's other drugs on the basis of volume (number of packs sold). The depreciation charge per pack is [✂] throughout the Infringement Period.

Total indirect costs per pack

Table A3.3: Indirect costs, as per CMA analysis of Advanz's costs

	2009	2010	2011	2012	2013	2014	2015	2016	2017
Common costs including expert support costs £000s	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Depreciation £000s	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Common costs per pack £s	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Depreciation per pack £s	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Total indirect costs per pack £s	**0.59**	**0.59**	**0.55**	**0.58**	**0.67**	**1.17**	**0.54**	**0.56**	**0.55**

Source: CMA Cost Plus assessment – 'Indirect cost allocation', 'Cost stacks post reps' tabs.

[51] The CMA has considered whether it would be appropriate to spread these costs over a longer period on the grounds that the benefit derived from them will persist beyond the period in which the costs were incurred. The CMA's analysis shows that spreading the costs over the remainder of the Infringement Period (i.e. over the period 2013–2017) has no material impact on the level of the Differential. If, alternatively, the CMA were to spread the expert support costs over a longer period so that not all of the costs were recognised in the period from 2013-2017, this would increase the level of the Differential in those years by comparison.

[52] CMA Cost Plus assessment – 'Indirect cost allocation' tab.

[53] Document LIO2945.10, Annex 11 to Advanz's response to the CMA's s.26 notice dated 26 May 2017.

D. Reasonable rate of return (the 'Plus')

3.59 When establishing the '*costs actually incurred*' it will normally be necessary to allocate a reasonable rate of return to cover the cost of capital, i.e. the 'Plus' element of Cost Plus.[54] The reasonable rate of return reflects the opportunity cost to investors of providing capital to Advanz to purchase assets and fund working capital requirements.

3.60 Where capital employed can be reliably measured, the return on capital employed ('ROCE') model is preferable to other estimates of a reasonable rate of return, such as profit margin measures (e.g. return on sales), because it considers how much capital investors have actually provided to the business when estimating what rate of return is reasonable.[55] By contrast, profit margins show how much profit is generated from £1 of revenue but not how much capital is required to generate that revenue or profit. They do not therefore indicate whether that profit is sufficient to cover the costs of generating that revenue. When comparing firms where the ratios of capital employed to revenue are very different, the level of profit required to compensate investors for the cost of the capital that they have put into the business would also be different.

3.61 In order to establish a reasonable rate of return in this case, the CMA has followed the ROCE model. The relevant data are available to measure both the capital employed and the cost of that capital (the weighted average cost of capital (WACC, see below)), which are the two inputs required to calculate the reasonable rate of return:

(a) Capital employed (or capital base): this is the amount of capital that Advanz had to deploy to operate in the UK Liothyronine Tablets market during the Infringement Period. This includes both tangible and intangible assets and working capital (deducting any amortisation or depreciation already charged).

(b) Cost of capital (or WACC): this is the average percentage return that debt and equity investors expect in return for providing funds to a company they have invested in.

3.62 The reasonable rate of return is therefore given by:

Reasonable rate of return = Capital employed x Cost of capital.

[54] See paragraph 5.126 of this Decision.

[55] The ROCE model has practical, real-world applications and is used extensively by businesses, investors, financial analysts and regulators to assess the appropriate rate of return. Businesses use the ROCE approach to appraise investment projects; financial analysts use it to measure risk and returns investors expect when investing in companies; and UK regulators use the ROCE to determine an appropriate rate of return when setting prices in regulated industries such as gas, electricity, and water.

3.63 In the remainder of this section, the CMA describes its approach to the valuation of capital employed and its approach to determining an appropriate rate of return for investors.

3.64 The costs associated with holding assets and working capital are reflected in the Cost Plus calculation in two different ways:

(a) Where an asset has a finite useful economic life ('**UEL**'), the costs of purchasing the asset are spread over the period during which the asset is used, via an annual depreciation or amortisation[56] charge. For example, where an asset has a 10-year UEL and it loses value at the same rate over time, 10% of its purchase price is expensed each year.[57] These elements are included in direct and indirect costs; and

(b) Both assets and working capital are included in the capital base of the firm (deducting any depreciation already charged). A rate of return – in this case, the WACC – is then applied to all capital employed. The WACC is the average return which debt and equity investors expect for providing funds to a company they have invested in. The return therefore reflects the opportunity cost to investors of providing capital to Advanz to purchase assets and fund working capital requirements. This return to investors is included in the 'Plus' part of the Cost Plus assessment.

I. The assessment of capital employed

3.65 The capital base (or capital employed) of a company includes both tangible and intangible assets and working capital (deducting any depreciation already charged by way of an amortisation or depreciation charge).

3.66 Assets included in a company's capital base are items such as buildings, machinery and intellectual property, while working capital is required to cover the day-to-day operational financing requirements of a business (e.g. stock, debtors, creditors).

3.67 The first step in determining the value of capital employed in the supply of Liothyronine Tablets is to identify the assets used in the supply of Liothyronine Tablets. The CMA asked Advanz to provide the value of its assets as at the end of each accounting period and for this information to be split by asset category. Advanz chose to split the costs into the following asset categories:

[56] Amortisation is the term for decreasing the recorded value of an asset over time to reflect its reduced worth. In the context of tangible assets amortisation is referred to as depreciation.
[57] Where straight line depreciation is applied.

(a) Land and buildings;

(b) Plant and machinery;

(c) Office equipment;

(d) Motor vehicles;

(e) Customer/Distributor relationship;

(f) Goodwill;

(g) Software;

(h) Patents and trademarks;

(i) Product Rights, licensing agreement, product brands, Know how; and

(j) Intellectual Property Research & Development.[58]

3.68 With the exception of the goodwill, customer/distributor/supplier relationships and patents and trademark asset categories, the CMA concludes that all of the other asset categories ought to be included in Advanz's capital base. Advanz included each of these asset categories under the heading '*attributable to Liothyronine'*[59] and the CMA has seen no evidence to indicate that these assets were not used in the supply of Liothyronine Tablets, with one exception relating to land and buildings. Advanz provided evidence identifying the value of land in India which is not used in the supply of Liothyronine Tablets.[60] The CMA therefore includes land and buildings in the asset categories listed in paragraph 3.67 above, with the exception of the land in India.

3.69 As described earlier, the CMA does not include the following three asset categories in its assessment of capital employed:

(a) Goodwill;

(b) Customer/distributor/supplier relationships; and

(c) Patents and trademarks.

[58] Document LIO4426, Advanz's response to the CMA's s.26 notice dated 6 September 2017.
[59] Document LIO4426, Advanz's response to the CMA's s.26 notice dated 6 September 2017.
[60] Document LIO2988.1, '*Annex 1 – Asset level breakdown (freehold land and buildings)'*.

d. Asset categories

Goodwill

3.70 When there were corporate transactions during the Infringement Period, Advanz conducted[61] a valuation of intangible assets in line with the relevant accounting standards.[62] Such an accounting exercise requires that the full purchase consideration be split among identifiable assets (both tangible and intangible) with the remaining balance attributed to goodwill. The balance recognised as goodwill therefore reflects an excess of the purchase consideration over the total value of identifiable assets at the time of purchase, including intangible assets such as Product Rights.[63]

3.71 Goodwill is not an asset that is required in order to supply Liothyronine Tablets. As such, the CMA has not included any amount in respect of goodwill when assessing the value of the assets on which Advanz earns a return.

Customer/distributor/supplier relationships

3.72 Advanz argues that a 'supplier relationship' asset valued at [✂] should be included.[64] Advanz claims that there are likely to be '*salary costs and other costs that would be required to enable a technology transfer from one supplier to another*'.[65] Its supplier relationship asset valuation, derived from the EY Report, is an estimate of the replacement cost that Advanz might have to incur to '*switch suppliers and generate a new relationship de novo'*.[66]

3.73 Advanz has subsequently removed a total of £4.7 million of the employee costs included in the 'Technical, regulatory and specific' cost category that relates to the '*formation of new supplier relationships for many of Concordia's products'* (but not for Liothyronine Tablets).[67] Advanz explains that *'inclusion [of those costs] would lead to double-counting with the supplier relationship asset'*.[68] However, Advanz has provided no direct evidence that it incurred any one-off costs to establish a new relationship with suppliers (either for Liothyronine Tablets or its other products) that were not already included in the 'Technical, regulatory and specific' cost category.

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[61] Or commissioned a third party to conduct.
[62] The relevant accounting standards that Advanz applied were IFRS 3 and IAS 38. See, for example, document LIO4937, EY Report, 16 September 2016, page 2.
[63] The CMA does not consider that the EY Report valuation of Product Rights is appropriate for determining the replacement cost valuation. See paragraph 3.136 below for more detail.
[64] Document LIO6361.3, First FTI Report, paragraph 5.28.
[65] Document LIO7786, Second FTI Report, paragraph 3.11.
[66] Document LIO7786, Second FTI Report, paragraph 3.11.
[67] See Advanz's response to CMA email dated 2 March 2021.
[68] See Advanz's response to CMA email dated 2 March 2021.

3.74 The CMA therefore considers that the most appropriate treatment is not to remove the £4.7 million of employee staff costs from 'Technical, regulatory and specific' cost category and allocate a proportion of those group level costs to Liothyronine Tablets as an 'indirect cost'. Under this approach, the CMA recognises a 'notional expense' using the actual costs incurred in forming supplier relationships for Advanz's other products as a proxy for the costs that might have been incurred for developing those supplier relationships for Liothyronine Tablets.[69]

3.75 The CMA notes that there is no reliable alternative benchmark, as neither Teva nor Morningside have incurred any one-off costs to form supplier relationships, as they manufacture their own products. The CMA does not consider that Advanz's valuation derived from the EY Report provides a suitable basis by which to determine the value of an asset for the purposes of an economic cost assessment, for the reasons set out in paragraphs 3.125 and 3.136 below. Advanz's derived supplier relationship intangible asset based on the EY Report is likely to be overstated for the same reasons as those for which Advanz's EY Report derived Product Rights valuation is likely to be overstated, i.e. the valuation is based on the actual and potential cashflows generated from the pricing conduct under investigation, which will likely lead to an inflation of the asset value simply because the cash flows are also likely to be inflated by the excessive pricing.

3.76 Given the lack of independent and reliable evidence that Advanz incurs one-off costs when it establishes a new supplier relationship, the CMA does not recognise such an asset in Advanz's capital base. Although no relevant costs were incurred during the Infringement Period, the CMA's Cost Plus, on a cautious basis, still allocates some costs that pertain to Advanz's supplier relationship with its CMO.

Patents and trademarks

3.77 The CMA has recorded nil values for the categories of 'patents and trademarks' and 'IPR&D' in line with the values for these categories submitted by Advanz.[70] This is consistent with the fact that Liothyronine Tablets are a generic drug and therefore not under patent and that Advanz has not carried out any research or development in respect of Liothyronine Tablets during the Infringement Period.

[69] See paragraph 3.174 below for more detail.

[70] Document LIO2671, Annex 4 to Advanz's response to the CMA's s.26 notice dated 27 February 2017.

e. Approach to asset valuation

3.78 Advanz has provided annual accounting estimates of asset values, including product rights, goodwill, working capital and plant and machinery.[71]

3.79 Following the 2017 SO, Advanz submitted that the EY Report, which included estimates of the fair value of product rights,[72] distributor relationships, supplier relationships, manufacturing know-how and an assembled workforce, could be used to estimate the capital employed.[73] The EY Report was prepared in September 2016 for financial reporting purposes following the acquisition of AMCo by Concordia Healthcare Corporation.

3.80 As explained in paragraph 3.68 above, the CMA concludes that the following categories ought to be included in Advanz's capital base:

(a) Land and buildings;

(b) Plant and machinery;

(c) Office equipment;

(d) Motor vehicles;

(e) Software; and

(f) Assets associated with Product Rights, including licensing agreements, product brands and Know-how.

3.81 In this section, the CMA describes its approach to estimating the value of the asset categories set out in paragraph 3.80 above.

3.82 One possible method of asset valuation is to use accounting values. These may be determined by reference to the 'gross book value' of an asset which is the acquisition cost (i.e. the costs actually incurred in purchasing or developing a specific asset) or the 'historical cost' in accounting terms. Another accounting measure is the 'net book value' which is historical cost less any amortisation or depreciation charged.

3.83 However, for the purposes of an economic cost assessment, the profits earned and capital employed should reflect the economic cost of the

[71] Document LIO4426, Advanz's response to the CMA's s.26 notice dated 6 September 2017.
[72] Product rights in this context are the intangible asset that collectively refers to the costs of obtaining the manufacturing knowhow and the final regulatory approval (i.e. the MA) required for the supply of Liothyronine Tablets (Product Rights).
[73] Document LIO4937, EY Report, page 24. See also document LIO6361.3, First FTI Report, paragraphs 2.12 and 5.17; document LIO6331, First Cinven CRA Report, paragraph 87; document LIO6259, First HgCapital CRA Report, paragraph 106.

resources involved. This may differ from the accounting values. The economic cost is the cost of resources used at a price at which they would be traded in a competitive market, where entry to and exit from the market is easy. Accounting values are often stated on a historic cost basis and may not equal the economic cost of the asset, particularly where the asset was purchased some time ago.

3.84 For capital assets, the economic cost should reflect their current value to the business, which is the loss the entity would suffer if it were deprived of the asset involved. That measure, which is also referred to as the deprival value, or value to the business, will depend on the circumstances involved.

3.85 The current economic cost of an asset (or a liability) may be determined by reference to:

(a) Entry value (replacement cost);

(b) Exit value (net realisable value); or

(c) Value in use (discounted present value of the cash flows expected from continuing use and ultimate sale by the present owner).

3.86 For some assets (for example, investments in actively traded securities), these three alternative measures of current value produce very similar amounts, with only small differences due to transaction costs. However, for other assets (for example, fixed assets specific to a business or product), differences between the alternative measures can be material.

3.87 Utilised assets should reflect their current value to the business, which is the loss the entity would suffer if it was deprived of the asset involved. Deprival value reflects the opportunity cost to the firm of owning that asset in a competitive market.

3.88 In most cases, as the entity will be putting the asset to profitable use within its current operations, the asset's value in its most profitable use (in other words, its recoverable amount) will exceed its replacement cost. In such circumstances, the entity will, if deprived of the asset, replace it, and the current value of the asset will be its current replacement cost.

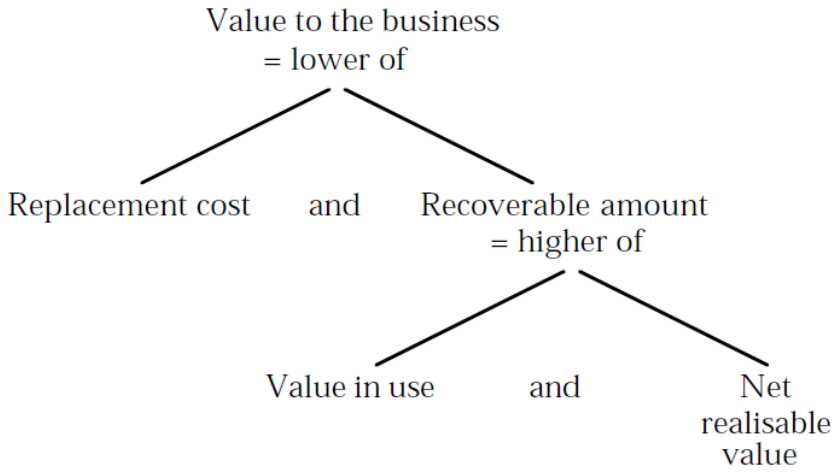
3.89 An asset will not be replaced if the replacement cost exceeds its recoverable amount. The recoverable amount is the higher of:

(a) The net realisable value of the asset – the sale amount less the costs of selling the asset; or

(b) The value in use – the net present value of continuing to use the asset in operations.

This can be portrayed diagrammatically as shown in Figure A3.1.

Figure A3.1: Establishing which valuation basis for an asset gives its value to the business



Source: UK Accounting Standards Board, Statement of Principles, 1999.

3.90 Application of these valuation principles is also called current cost accounting.

3.91 While the CMA considers that the correct measurement basis is the current value to the business, in certain cases the CMA has used proxies where it considers that these are unlikely to differ significantly from the value to the business basis. These include historical cost, which may be a good proxy where asset lives are short (e.g. computer equipment) and costs have not changed much (i.e. when inflation is low).

f. Product Rights

3.92 In order to supply Liothyronine Tablets in the UK it is necessary for the supplier to possess the relevant MA and to have access to the technical knowledge of how to produce Liothyronine Tablets. Product Rights is the term used to describe intangible assets relating specifically to the regulatory approval (i.e. the grant of the MA) and technical know-how required for the supply of Liothyronine Tablets.

3.93 The CMA has considered:

(a) Whether it is appropriate to recognise Product Rights as an asset within Advanz's capital base; and

(b) If so, what approach it should take in order to establish an appropriate value for the Product Rights.

3.94 To obtain an MA, a prospective supplier must compile a dossier detailing its proposals for how it will obtain and market the drug in question. This dossier must include detailed technical information as to the manufacture of the drug that the prospective supplier proposes to sell. Once the prospective supplier has submitted the dossier to the MHRA it must pay an application fee and respond to any follow-up questions the MHRA may ask. The CMA recognises that this process will have a cost associated with it and that this is an unavoidable cost that any prospective supplier must incur in order to enter the market for the supply of Liothyronine Tablets in the UK. The CMA is also aware that it may be necessary for a party seeking an MA to conduct clinical trials in support of its MA application. The CMA therefore considers it reasonable to include an amount in respect of the cost of obtaining an MA as an asset within Advanz's capital base.

3.95 In estimating the replacement cost of the MA, the CMA considers that manufacturing know-how is required in order to get the MA and that collectively the costs associated with obtaining the know-how and therefore the MA represent the costs of obtaining the Product Rights required in order to supply Liothyronine Tablets. This approach is consistent with the submissions of both HgCapital and Cinven. For example, Cinven stated:

> '*CRA's analysis attempts to calculate a conservative estimate of the value of intangible assets (termed "Product Rights" in the 2017 SO) associated with Liothyronine Tablets. It is not necessary to distinguish between different "types" of intangible associated with the production of Liothyronine Tablets, as there is no reason to believe that they should be treated differently for the purposes of the cost calculation. In reality any distinction is likely to be artificial: an MA can only be obtained if an entrant can show bioequivalence, which in turn requires there to be a capability to manufacture to that bioequivalent standard*.'[74]

3.96 Advanz, on the other hand, submitted that the know-how intangible was separate from the MA. Advanz stated that obtaining the know-how required to produce a drug was a separate workstream from obtaining the MA.[75]

3.97 The CMA concludes that in practice this distinction is not particularly pertinent to the task of estimating the costs of supplying Liothyronine Tablets. As long as the value of both the know-how and the MA are considered in the Product Rights valuation, the cost estimate will be complete, regardless of whether

[74] Document LIO6587, Cinven's response to question 1 of the CMA's s.26 notice dated 7 June 2018.
[75] Document LIO6664, Advanz's response to question 7 of the CMA's s.26 notice dated 7 June 2018.

they are valued collectively as a single product right asset or separately as the know-how and MA assets.

Approaches to valuing the Product Rights intangible asset

3.98 As set out in paragraph 3.78 above, one possible method of asset valuation is to determine the costs incurred by Advanz in obtaining the relevant assets, i.e. the actual acquisition costs (referred to as 'historical cost' in accounting terms). However, the CMA considers that in this case, the acquisition cost is unlikely to reflect the true economic cost of the Product Rights for Liothyronine Tablets for the following reasons:

(a) The value of the Product Rights is likely to have changed materially over time. The MHRA has told the CMA that regulatory requirements for the award of an MA for Liothyronine Tablets have increased in complexity since 1992.[76] The stricter regulatory requirements associated with the award of an MA mean that a potential entrant during the Infringement Period would have likely had to pay more to obtain an MA for Liothyronine Tablets than Advanz paid to acquire the MA in 1992.

(b) It is not straightforward to calculate the proportion of the £1 million actual portfolio acquisition cost attributable to Liothyronine Tablets.[77] The CMA could allocate the actual acquisition costs using volume, that is the number of packs sold, resulting in an acquisition cost of about £10,000.[78] However, this would rely on assumptions on the allocation that are likely to be difficult to support. The CMA could also simply err in Advanz's favour and use the whole £1 million acquisition cost (i.e. a substantially larger amount than a reasonable allocation of the £1 million to Liothyronine Tablets) but this approach would also be based on unsupported assumptions.

(c) In any event, as explained in paragraph 3.83 above, the acquisition cost itself may have limited resemblance to the economic cost of Product Rights during the Infringement Period.

3.99 The CMA therefore uses the 'value to the business' approach, and more specifically 'replacement cost' as the approach to determine the value

[76] See paragraph 3.98 of this Decision.

[77] The actual acquisition cost in this case is the amount actually paid by Advanz to acquire the Product Rights for Liothyronine Tablets. Advanz paid Medeva £1 million to obtain a portfolio of 22 products in 1992 which included Liothyronine Tablets.

[78] Advanz provided data in document LIO2945.12, '*Medeva products portfolio*', showing that Liothyronine Tablet sales have amounted to approximately 1%, by volume, of the sales of all products acquired as part of the portfolio. This would suggest that the share of the acquisition cost attributable to Liothyronine Tablets would be of the order of £10,000. This figure is calculated by reference to sales volumes. Allocating by the number of products i.e. £1 million/22 would suggest a share of the acquisition cost attributable to Liothyronine Tablets of £45,455. The CMA's Cost Plus valuation of Product Rights of [✂] is approximately [✂] times higher than this.

(economic cost) of Advanz's Product Rights in this case by using the valuation techniques underpinned by the 'value to the business' approach. Using this approach requires the CMA to assess the amount that Advanz would have had to pay in order to acquire (or replicate) the Product Rights during the Infringement Period, i.e. the replacement cost. Given there has been recent, successful entry in the market (shortly after the end of the Infringement Period), the CMA has undertaken further analysis to estimate the efficient costs of obtaining the Product Rights.

3.100 As explained in Figure A3.1 above, under the 'value to the business' approach, the value of assets is defined as the lower of:

(a) Replacement cost; and

(b) Recoverable amount (which is the greater of (i) the selling price less the costs of selling the asset; and (ii) value in use).[79]

3.101 In the circumstances of this case, the lower amount is the replacement cost. This is because the recoverable amount is calculated by reference to the present value of cashflows generated during the Infringement Period. This is likely to be very high, and significantly higher than the costs associated with replacing the Product Rights, as the cashflows during the Infringement Period are likely to be inflated by the pricing conduct under investigation. Using the recoverable amount would likely distort the value of Product Rights upwards.

3.102 Accordingly, the CMA does not consider that the use of the recoverable amount to value Product Rights is appropriate in this case. Two of the Parties' alternative valuation methodologies are premised on determining the value of Product Rights with reference to the recoverable amount. The CMA explains in more detail in paragraph 3.125 below why this is inappropriate.

The CMA's replacement cost valuation of Product Rights – [✂]

3.103 The replacement cost is not directly observable as Advanz has not recently replaced its MA for Liothyronine Tablets. To estimate replacement costs, the CMA assesses the amount that Advanz would have had to pay in order to acquire (or replicate) the Product Rights during the Infringement Period. Therefore, the CMA has assessed how much successful new entrants have spent, in order to obtain the Product Rights needed to enter the Liothyronine Tablets market. Their actual costs are likely to represent the most appropriate estimate of the efficient replacement cost of Product Rights.

[79] Value in use is a term that describes the present value that a company can generate through ongoing use of an asset until the asset is no longer useable.

3.104 There have been two successful new entrants in the Liothyronine Tablets market to date, namely Teva and Morningside. Morningside incurred costs of [✂] to enter the UK market for Liothyronine Tablets.[80] Teva estimates that its costs ranged from [✂] to [<£1 million]. The CMA has used the upper end of Teva's entry cost estimate range of [<£1 million] as the value for Product Rights for the purposes of Cost Plus. The CMA, on a cautious basis to reflect the potential uncertainties, has not only chosen the higher of the cost estimates provided by the two entrants but also adopted the upper end of the higher cost estimate, i.e. Teva's upper end estimate of [<£1 million]. This approach is favourable to the Parties.

3.105 The CMA asked the two entrants to provide information on the costs that were incurred to enter the market for the manufacture and/or supply of Liothyronine Tablets in the UK, including any relevant costs associated with the development of the product, developing/sourcing manufacturing capability, obtaining an MA and setting up a distribution network.

Morningside

3.106 Morningside initially submitted that it had incurred costs '*in the region of* [✂] *(including the £10,000 fee payable for the MA application)*' to enter the UK Liothyronine Tablets market.[81] This figure related only to the '*fixed costs'* incurred; Morningside could not readily cost *'the time invested in the development of the product between 2012 (when development work began) and June 2017 when an MA was finally granted'*.[82]

3.107 In response to the CMA's clarificatory questions, Morningside confirmed that the [✂] entry cost estimate related only to '*external, third party costs and did not cover any internal costs'*.[83] It explained that these costs covered the external costs associated with '*developing the know-how to manufacture tablets, including all related research and development costs, developing the manufacturing capability and obtaining the MA'*.[84] Morningside confirmed that it had not included the costs of setting up a distribution network as these costs were not borne by it.[85]

3.108 Morningside confirmed that its [✂] estimate did not include costs related to the '*internal time of MHL employees or any consultants, as their involvement*

[80] Document LIO12168, Morningside's response to CMA's s.26 notice dated 18 February 2021.
[81] Document LIO3232, Morningside's response to question 5 of the CMA's s.26 notice dated 7 July 2017.
[82] Document LIO3232, Morningside's response to question 5 of the CMA's s.26 notice dated 7 July 2017.
[83] Document LIO12168, Morningside's response to question 1 of the CMA's s.26 notice dated 18 February 2021. Morningside provided a breakdown of the relevant external costs: (i) [✂] of development costs; (ii) [✂] of API costs; (iii) [✂] of manufacturing development costs; (iv) [✂] of clinical studies; and (v) [✂] of registration costs.
[84] Document LIO12168, Morningside's response to question 1 of the CMA's s.26 notice dated 18 February 2021.
[85] Document LIO12168, Morningside's response to question 1 of the CMA's s.26 notice dated 18 February 2021.

in the Morningside business is across a wide spectrum of projects'.[86] Morningside submitted that it '*does not internally record individuals time on a timesheet basis'* and this is why it could not '*readily directly attribute internal costs'*.[87] Morningside confirmed that the excluded costs related to activities associated with supporting its development and manufacturing partners in developing the know-how and manufacturing capabilities as well as the internal costs associated with bringing the product to market.[88]

3.109 Although Morningside submitted that it would not be possible to quantify these costs precisely, Morningside estimated that the internal costs [✂].[89] In reaching this figure, Morningside considered that, [✂] was required and this would include the development, regulatory, project management, advisory and support in negotiating with partners.[90]

3.110 The CMA considers that the internal costs associated with developing the know-how to manufacture Liothyronine Tablets are relevant to determine the complete replacement cost of Product Rights and should be included in Morningside's entry cost estimate.[91] Morningside's total entry cost is therefore [✂], derived by adding its internal cost estimate of [✂] to Morningside's initial entry cost estimate of [✂].[92]

Teva

3.111 Teva initially submitted that it had spent [✂] up to the point it applied for its MA in January 2017. Subsequently, Teva said it incurred additional costs of [✂], to address the MHRA's technical requirements to secure the MA, leading to total entry costs of [✂].[93,94] Teva submitted that its entry costs included the direct costs associated with Liothyronine Tablets, which included the costs relating to:

[86] Document LIO12168, Morningside's response to question 3 of the CMA's s.26 notice dated 18 February 2021.
[87] Document LIO12168, Morningside's response to question 3 of the CMA's s.26 notice dated 18 February 2021.
[88] Document LIO12168, Morningside's response to question 3 of the CMA's s.26 notice dated 18 February 2021.
[89] Document LIO12168, Morningside's response to question 3 of the CMA's s.26 notice dated 18 February 2021.
[90] Document LIO12168, Morningside's response to question 3 of the CMA's s.26 notice dated 18 February 2021.
[91] The Parties claim that Morningside's entry costs are understated as it has no provision for overhead costs. As Morningside operates a 'virtual' business and commissions its R&D from third parties, the type of overhead costs that it may have incurred such as corporate overheads have already been accounted for in the CMA's Cost Plus, as an 'indirect cost' (based on Advanz's overhead costs). Including the same overhead costs within Morningside's cost estimate would therefore lead to double-counting.
[92] Advanz argues that Morningside's costs are unreliable, and, it alleges, the low costs may be explained by '*its manufacturer in India not operating a compliant development/manufacturing facility*' (document LIO12198, Advanz's response to the Fourth Letter of Facts, paragraph 2.18). The CMA observes that, notwithstanding Advanz's allegations, the MHRA granted Morningside an MA.
[93] Document LIO3870, Teva's response to question 5 of the CMA's s.26 notice dated 6 September 2017.
[94] Similarly, Morningside also incurred additional costs during the MHRA process in responding to 'deficiency letters'.

(a) research & development, including the costs of the API, biostudies, laboratory chemicals, etc);[95]

(b) filing fees;[96]

(c) cost of goods; and

(d) waste product write-offs and the associated costs of destruction.[97]

3.112 Teva noted that it incurs a number of overhead costs that are '*not allocated to specific products but instead are borne by the business at a portfolio level'*.[98] These costs include *'the general costs associated with the running of a global pharmaceuticals business such as the staff and infrastructure required; facilities costs, as well as warehousing and distribution; regulatory fees associating with renewals of marketing authorisations, complying with regulatory obligations (e.g. pharmacovigilance); as well as other costs such as sales and marketing expenses'*.[99]

3.113 The Parties submitted that Teva's entry costs were understated but did not specify which aspect of Teva's costs was likely to be understated.[100] In response to the Parties' representations, the CMA asked Teva to reassess the completeness of its cost estimate and to include any costs that had not been included in the [✂] figure that related to (i) specific staff hired or fully allocated to production of Liothyronine Tablets; (ii) associated with developing the in-house manufacturing 'know-how' for supplying Liothyronine Tablets; and (iii) any Liothyronine-specific marketing costs. Teva confirmed that its [✂] was complete and that it was '*not aware of any further Liothyronine-specific costs that were incurred in order to enter the Liothyronine Tablet market, in addition to the information that Teva has already provided'* while also confirming that the estimate did not include 'overhead costs' that are incurred at the portfolio level.[101]

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[95] At the end of January 2017, Teva had incurred [✂]. As explained, Teva incurred additional costs while addressing the MHRA's regulatory requirements. Once it had secured the MA, Teva confirmed that it had incurred [✂] in research & development costs.

[96] Teva submitted that it had incurred [✂].

[97] Document LIO3870, Teva's response to question 5 of the CMA's s.26 notice dated 6 September 2017.

[98] Document LIO7456, Teva's response to question 15 of the CMA's s.26 notice dated 21 August 2018.

[99] Document LIO2195, Teva's response to question 13 of the CMA's s.26 notice dated 25 January 2017.

[100] Advanz submits that the total cost quoted for reformulating Levothyroxine was [✂]. Advanz argues that the fact that the projected reformulation costs significantly exceed the actual costs reported by Teva and Morningside to develop Liothyronine Tablets, suggests that 'material costs are not included in their estimates'. The CMA disagrees. It considers it appropriate to rely on the actual reported costs incurred by Teva to develop the know-how of Liothyronine Tablets, the product under consideration, rather than the expected costs that might be incurred by Advanz on some unrelated activity on an entirely different product (see document LIO7786, Second FTI Report, paragraphs 3.52–3.54).

[101] Document LIO7456, Teva's response to question 15 of the CMA's s.26 notice dated 21 August 2018.

3.114 The CMA's Cost Plus already includes an allocation for Advanz's overhead costs (as 'indirect costs') for categories such as corporate overheads. Including the same category of overheads within Teva's cost estimate would lead to double-counting as these types of costs have already been accounted for elsewhere. The CMA therefore considers that the only element of Teva's costs that might be understated and is likely to be relevant to the Product Rights valuation are those overhead costs that relate to Teva's research and development function, and specifically the costs that relate to the development of Liothyronine Tablets, as these are a category of overhead costs that is not incurred by Advanz and not already accounted for within the CMA's Cost Plus. To assess whether Teva's overhead costs included any relevant costs related to the development of Liothyronine Tablets that had not already been included in the [✂] estimate, the CMA asked Teva:

(a) Whether the overhead costs that were not included in Teva's original estimate of [✂] related to:

(i) developing the know-how to manufacture Liothyronine Tablets, including all related research and development costs (e.g. costs that relate to the management of the R&D function, internal R&D staff costs);

(ii) developing and/or sourcing manufacturing capability;

(iii) obtaining the MA; and

(iv) setting up a distribution network.

(b) To provide an estimate of any overhead costs that related to activities set out in (i) to the extent that those costs had not already been accounted for in Teva's initial entry cost estimate of [✂].

3.115 Teva informed the CMA that the principal research and development work in relation to the Liothyronine Tablets sold by Teva UK was undertaken [✂].[102] Following further investigation, Teva said that:

(a) [✂] had identified a *'number of Liothyronine specific costs totalling* [✂]*'* in relation to a) the procurement of API and other raw materials; b) certain batch costs; c) biostudies; and d) other services. However, Teva submitted it was '*unable to confirm* [✂]*'*.[103] That is to say, Teva was unable to confirm whether the addition of the [✂] would lead to double-counting.

(b) [✂] incurred R&D staffing costs in relation to:

(i) specific projects (but not liothyronine); and

[102] Document LIO12185, Teva's response to CMA's s.26 notice dated 2 March 2021.
[103] Document LIO12185, Teva's response to question 1 of the CMA's s.26 dated 2 March 2021.

(ii) general regional projects.[104]

3.116 Based on this information Teva submitted that '[✂] *incurred R&D related staffing costs in* [✂] *of c.* [✂] *per annum, and c.* [✂] *in* [✂]*'*.[105]

3.117 Based on the totality of the information provided by Teva, the CMA estimates that Teva's entry costs are likely to range between [✂] and [✂]. Table A3.4 sets out a detailed breakdown of the CMA's derived estimated range. Teva confirmed that the CMA's range reflects Teva's understanding of the data and that it was not aware any other directly attributable costs associated with the development of Liothyronine Tablets that should be included in the CMA's calculations.

Table A3.4: CMA's derivation of Teva's entry cost information

[✂]

3.118 The primary driver of the change in Teva's initial entry cost of [✂] relates to the identification of Liothyronine Tablets specific costs at [✂] of [✂]. Teva was not able to confirm whether these costs were already included in the original estimate of [✂].

3.119 [✂] R&D costs are likely to be genuine additional costs and would amount to [✂] if allocated by project and [✂] if allocated by molecule.[106] If the [✂] Liothyronine Tablets specific costs identified had already been included in Teva's initial estimate, Teva's revised entry cost estimate would have increased from [✂] to approximately [✂] (if R&D costs were allocated by project) or to approximately [✂] (if the R&D costs were allocated by molecule).

3.120 However, on a cautious basis, the CMA has adopted the upper end of the entry cost estimate of [<£1 million] for the purposes of the Product Rights valuation. Teva's updated entry cost estimate therefore includes:

(a) The [✂] of costs identified by Teva that may already have been included in Teva's original estimate of [✂]; and

(b) A proportion of the R&D staff costs incurred at [✂] for the period between October 2014 and August 2017, allocated by the number of molecules developed in each respective year, rather than by the number of projects. This

[104] Document LIO12185, Teva's response to question 1 of the CMA's s.26 dated 2 March 2021.
[105] Document LIO12185, Teva's response to question 1 of the CMA's s.26 dated 2 March 2021.
[106] Cinven submits that all of the R&D overhead costs incurred at [✂] should be allocated to Liothyronine Tablets, if '*nearly all joint staffing costs would be necessary to create a viable Liothyronine product*' (document LIO12197, CRA Report in response to the Fourth Letter of Facts, paragraph 22). The CMA does not consider it appropriate to allocate the entire pool of common and joint costs to one product when a number of other products were being developed at the facility at the same time.

is a more conservative assumption and allocates no costs to Teva's general projects undertaken in each of those years.

3.121 The CMA notes that there is a material difference between the entry cost estimates of the two successful entrants, with Morningside and Teva incurring [✂] and [<£1 million] respectively. The difference in the entry cost estimates could be due to the adoption of alternative business models: Morningside operates as a 'virtual business', [✂],[107] while Teva developed the know-how through its own research and development [✂].

3.122 It may be the case that Morningside's entry costs are more likely to reflect the costs that Advanz would have incurred had it been required to replicate Product Rights during the Infringement Period. This is because Advanz does not have a significant internal R&D function and may have been more likely to commission a third-party development house than developing Liothyronine Tablets internally. Notwithstanding this consideration, on a cautious basis, the CMA uses the higher (and upper end) of the entry cost estimates of the two successful entrants to value the Product Rights of Liothyronine Tablets, that is Teva's entry costs of [<£1 million]. This approach is highly favourable to the Parties.

Parties' alternative methodologies to value Product Rights

3.123 The Parties argue that the CMA's Product Rights replacement cost valuation based on actual entrants' costs is understated and propose three alternative measures to estimate the value of Product Rights: (i) top-down valuation based on Globalview's Report; (ii) valuation derived from EY Report; and (iii) probability adjusted *ex ante replacement cost* to account for a possible risk of failure.[108]

3.124 The purpose of the Product Rights assessment is to provide a meaningful, reliable and objective measure of the costs that would be incurred to acquire or replicate the Product Rights of Liothyronine Tablets. The CMA has assessed the Parties' proposals with this purpose in mind.

3.125 As explained in more detail in paragraphs 3.127 to 3.136 below, the CMA considers that the first two valuation methodologies proposed by the Parties are not appropriate for the following reasons:

(a) The valuations derived from the Globalview and EY Report depend on the net present value of future cashflows of Liothyronine Tablets (i.e. the net

[107] Document LIO2017, Morningside's response to the CMA's s.26 notice dated 25 January 2017.
[108] Document LIO6331, First Cinven CRA Report; document LIO6258, HgCapital RSO; document LIO6259, First HgCapital CRA Report.

realisable value of Product Rights) based on the prices charged during the Infringement Period. This is inappropriate for two reasons:

(i) In a case of excessive pricing, determining the value of an asset based on the actual and potential cashflows generated from the pricing conduct under investigation will likely lead to an inflation of the asset value simply because the cash flows are also likely to be inflated by the excessive pricing. This biases the value of Product Rights upwards.

(ii) Using the net realisable value of Product Rights departs from the replacement cost framework. Under the 'value to the business' approach, the accounting principles require the asset value to be the lower of replacement cost and net realisable value. In the circumstances of this case, the replacement cost would always be lower than the net realisable value as the latter measure reflects the supernormal profits reaped by Advanz during the Infringement Period.

(b) The CMA therefore considers that the Parties' proposed methodologies are inherently flawed and inappropriate for an excessive pricing case, as they lead to a valuation of Product Rights that is likely to be distorted by the pricing conduct under investigation. Notwithstanding these methodological concerns, the CMA has considered the Parties' alternative valuations which range between £6.2m and £36.7m. These valuations are orders of magnitude higher than the actual costs incurred by firms to successfully enter the market. For example, the lower end of the Parties' valuation range is [✂] the highest amount incurred by a firm that has entered successfully (i.e. Teva's entry cost of [✂]), and the upper end of the Parties' valuation range is [✂] this amount. In comparison to Morningside's entry costs, the multiples of the lower and upper end of the Parties' valuation range are higher [✂]. The significant difference between the CMA's estimate – which is based on objective and independent evidence from actual entrants – and the Parties' valuations confirms that no weight should be placed on either of the valuation approaches proposed by the Parties. In the CMA's view, they do not reflect a meaningful replacement cost valuation, particularly when successful entrants have developed Liothyronine Tablets for [✂].

3.126 For these reasons, the CMA considers that the Parties' proposed valuations do not provide an appropriate or accurate basis for determining the value of Product Rights for the purposes of an economic cost assessment. With respect to the third alternative measure – a probability adjusted replacement cost – the CMA considers that it may provide a useful cross-check to the CMA's Product Rights valuation based on actual entrants' costs and it is therefore included as a sensitivity to the CMA's Cost Plus. The CMA considers the Parties' proposed valuations in further detail in paragraphs

3.127 to 3.136 below. A detailed analysis of the CMA's sensitised replacement cost is found in paragraphs 3.187 to 3.218 below.

Top-down valuation based on Globalview's Report

3.127 In response to the 2017 SO, both Cinven and HgCapital argued that an alternative, more appropriate method of valuing Product Rights would be a top-down valuation that estimates the net present value ('**NPV**') of revenue streams associated with entry.[109,110]

3.128 The Parties suggest using Globalview's valuation of the Product Rights for Liothyronine Tablets sold in the UK. Globalview's calculation of the NPV of Liothyronine Tablets was carried out on behalf of Cinven in 2012, in the context of Cinven's acquisition of Mercury Pharma Group Limited from HgCapital. The Parties note that this valuation was carried out '*in the normal course of business*' on behalf of a sophisticated private equity firm while preparing its financial statements.[111]

3.129 In order to avoid a 'circular' NPV of Product Rights which is based on allegedly excessive, anticipated future prices, the Parties also suggest the following alternative competitive levels of pricing as the basis for the calculation:[112]

(a) £30 per pack – which the Parties argue is the minimum price that would generate entry. This price applied during FY13 would lead to a Product Rights valuation of £15.3m.

(b) £45 per pack – which corresponds to Teva's predicted price of [✂] with three or to four competitors and to [✂], which was the price in 2012 when Morningside began its development process. This price applied during FY13 would lead to a Product Rights valuation of £23m.

(c) £75 per pack – which corresponds to Teva's [✂] based on a [✂]. This price applied during FY17 would lead to a Product Rights valuation of £36.7m.

3.130 In each of these scenarios, the Parties' approach uses price as the relevant measure for estimating the value of Product Rights. As explained in paragraph 3.101 above, this leads to a circularity in reasoning as the net present value

[109] Document LIO6331, First Cinven CRA Report, paragraph 80; document LIO6258, HgCapital RSO, paragraph 110(f); document LIO6259, First HgCapital CRA Report, paragraph 93(b).
[110] The top-down valuation estimates the 'net realisable value', and specifically the 'value in use' of Products Rights.
[111] Document LIO6331, First Cinven CRA Report, footnote 57; document LIO6259, First HgCapital CRA Report, paragraph 93(b).
[112] Document LIO6331, First Cinven CRA Report, paragraph 81; document LIO6330, Cinven RSO, paragraph 9.15; document LIO6259, First HgCapital CRA Report, paragraph 97.

calculation derived from the Globalview valuation is dependent on cashflows generated by prices charged during the Infringement Period. In a case of excessive pricing, determining the value of an asset based on the actual and potential cashflows generated from the pricing conduct under investigation will likely lead to an inflation of the asset value simply because the cash flows will also likely be inflated by the excessive pricing. The Parties' alternative of picking random points on the price curve does not address the circularity either, as the lowest of those price points (£30) is almost 1,300% above the average cost of production (direct and indirect).[113]

3.131 For these reasons, the CMA does not regard the top-down valuation based on NPVs to be an appropriate or a relevant methodology to value Product Rights.

3.132 To avoid any circularity of reasoning, the CMA considers that cost rather than price is the more appropriate measure to use in excessive pricing cases when determining inputs into the Cost Plus assessment. The CMA's replacement cost estimate is based on objective and independent evidence that reflects the actual costs incurred by companies that have entered the market in recent years. The CMA therefore adopts replacement cost as the relevant measure.[114]

Valuation derived from the EY Report

3.133 Following the 2017 SO, the Parties argued that an alternative Product Rights valuation could be derived from the EY Report produced on behalf of Concordia Healthcare Corporation in the context of its acquisition of AMCo. The report estimated the value of intangible assets, and it included a valuation of the Product Rights associated with hard-to-make ('H2M') drugs (such as Liothyronine Tablets). The EY Report valued the Product Rights of the entire H2M portfolio, consisting of [✂] products, at [✂]; which provides an average value per product of [✂].[115,116] The average value per product is based on the assumption that the replacement of each product would take 24 months.

3.134 The Parties, however, state that the EY Report would understate the value of the product rights for Liothyronine Tablets because actual entry took around

[113] The average cost of production per pack (including both direct and indirect costs) during the Infringement Period was £2.18 per pack (see Table A.3.7 below). In the long run, prices would be expected to be close to the underlying costs of production: see Section 5.E.IV.a.ii of this Decision ('*Prices in mature generics markets*').
[114] The accounting standards require the lower of replacement cost and net realisable value to be adopted as the relevant valuation measure.
[115] Document LIO4937, EY Report.
[116] Document LIO6361.3, First FTI Report, paragraph 5.14; document LIO6331, First Cinven CRA Report, paragraph 87; document LIO6258, HgCapital RSO, paragraph 110(f); document LIO6259, First HgCapital CRA Report, paragraph 105.

five years. As a result, they propose to apply a multiplier of [✂] to reflect this [✂]. This results in a valuation of [✂].[117]

3.135 HgCapital and Cinven say that it is not clear from the EY Report whether its valuation includes the costs of obtaining an MA (i.e. cost of bioequivalence studies and/or filing fees). They argue that the true value may therefore be higher than [✂].[118]

3.136 The CMA considers that it is inappropriate to derive a Product Rights valuation using the EY Report for the following reasons:

(a) The EY Report was prepared solely for financial reporting purposes to help Advanz's management with the allocation of the Excess Purchase Consideration or the purchase price discrepancy, which is the difference between the amount paid for AMCo [✂] and the value of net assets of the business [✂] when it was acquired from Cinven in October 2015.[119] The valuation of the assets is premised on an acquisition price of [✂] and based on information and data from Advanz's management that EY did not independently investigate or verify.[120] The 'fair value' valuations on which the EY Report is based also reflect the '*probability that the future economic benefits associated with the asset will flow to the acquirer*', that is, the net present value of Product Rights that is contingent on the prices charged during the Infringement Period.[121] As explained in paragraph 3.125 above, this approach is inappropriate in an excessive pricing case, as the asset value is likely to be inflated as a result of the inflated cashflows resulting from the pricing conduct under investigation.

(b) Advanz has since made impairments to the value of the intangible assets that were allocated a value by the EY Report. By implication, the value of the Product Rights of Liothyronine Tablets, if valued at a later date, would likely be lower than estimated in October 2015. The replacement cost of Liothyronine Tablets should not rise and fall depending on the value of the whole business but instead should be valued on the basis of the actual costs involved in developing the necessary know-how.

(c) The EY Report does not attempt to value Liothyronine Tablets in isolation but estimates the value of 'know-how' for a group of 'hard to make' drugs based

[117] Document LIO6331, First Cinven CRA Report, paragraph 87; document LIO6330, Cinven RSO, paragraph 9.16; document LIO6259, First HgCapital CRA Report, paragraph 106; document LIO6361.3, First FTI Report, paragraph 5.16.
[118] Document LIO6331, First Cinven CRA Report, footnote 71; document LIO6259, First HgCapital CRA Report, paragraph 107.
[119] Document LIO4937, EY Report, page 4.
[120] Document LIO4937, EY Report, page 3.
[121] Document LIO4937, EY Report, page 7.

on discussions with management. The CMA notes that Advanz did not develop the know-how for Liothyronine Tablets in-house but acquired the MA in 1992. Advanz's management therefore has no direct experience of developing this know-how. The CMA's estimate, conversely, is based on objective and independent evidence from successful entrants that have recently incurred costs to develop the necessary 'know-how' to manufacture/supply Liothyronine Tablets.

(d) In addition to point c) above, the CMA notes that the derived valuation from the EY Report is orders of magnitude higher than the actual costs incurred by successful entrants. Given the significant difference between the Parties' valuation based on an October 2015 acquisition price and the objective and independent cost information from actual entrants, the CMA considers that the EY report valuation does not provide a reliable or reasonable proxy for the replacement cost. In the CMA's judgement, no weight should be placed on the EY Report valuation.

(e) The Parties apply an uplift of [✂] to the 'average' EY Report valuation of [✂] per product, to reflect the additional time, they say, it would take to develop the know-how of Liothyronine Tablets. The basis of the uplift is the time taken by actual entrants to develop their know-how. Not only is the starting figure inflated, for the reasons given above, but the Parties also assume, without evidence, that the cost of Product Rights varies strictly in proportion to time: in the CMA's view, the timescale and the time profile of costs are likely to be more dependent on the specific measures required to satisfy the MHRA and the strength of the company's desire to achieve entry.[122] The CMA considers that it is more appropriate to make use of objective evidence from independent third parties than to rely on a hypothetical valuation based on unverifiable and unsubstantiated assumptions.

The probability adjusted ex ante replacement cost

3.137 With respect to the Parties' third alternative valuation methodology – the probability adjusted *ex ante replacement cost* – the CMA does not consider that an adjustment to its Cost Plus replacement cost estimate is required, as it is based on objective and independent data from actual successful entrants. Nonetheless, in response to the Parties' representations and to provide a cross-check on the CMA's replacement cost valuation, a sensitivity analysis is carried out on the value of Product Rights. More detail on the Product Rights sensitivity can be found below in section A3.F.II below.

[122] By way of context, the CMA uses Teva's entry costs of [<£1 million] instead of Morningside's lower cost of [✂]. Teva incurred higher costs than Morningside but completed its entry in two fewer years (three years instead of Morningside's five years).

g. Fixed assets

3.138 Advanz also employs fixed assets and has categorised them as shown in paragraph 3.67 above. The fixed assets relate to those employed by the corporate group as a whole, a proportion of which is notionally attributable to Liothyronine Tablets.[123]

3.139 In determining the value of capital employed, the CMA needs to determine the value of these assets. Assets are recorded in accounting records where their values are known as net book values. Net book values may or may not be an accurate reflection of an asset's true value.[124]

3.140 Net book values for assets recorded using the cost model[125] reflect the original purchase cost less an amount in respect of depreciation.

3.141 The CMA concludes that, where the useful economic life (UEL) that Advanz uses to depreciate fixed assets for accounting purposes is reasonable, the net book value provides a reasonable proxy for depreciated replacement cost.[126] In the case of relatively short life assets such as motor vehicles and computer equipment, the scope for inaccuracy in the estimation of UELs is so limited that it is unlikely to materially affect the net book value of the asset. In such a context the net book value provides a readily available estimate of value which is not likely to be materially inaccurate.

3.142 Therefore, the CMA concludes that it is reasonable to use net book values as a proxy for the efficient cost of these assets to Advanz.[127] These book values have been allocated on the basis of volume (number of packs sold), which is a reasonable approach in the circumstances of this case (see paragraphs 3.36 to 3.48 above for a discussion of appropriate cost drivers).

h. Working capital

3.143 Working capital is the amount of capital that is employed in financing short-term assets, net of the capital provided by short-term liabilities. Working capital is

[123] This category includes assets described by Advanz as *'land and buildings, plant and machinery, office equipment, motor vehicles and software'*. For completeness, Advanz reported nil values for the following categories in respect of Liothyronine Tablets: customer/distributor relationship, patents and trademarks, IP R&D. See document LIO4426, Advanz's response to the CMA's s.26 notice dated 6 September 2017.

[124] For example, if the useful economic life over which it is being depreciated does not reflect its actual economic life.

[125] The *'cost model'* is one of two models for valuing fixed assets (the other being the *'revaluation model'*) as described in accounting standard IAS 16.

[126] This point follows from the fact that, where the depreciation policy is broadly in line with the economic depreciation, the net book value of assets will represent the amount that the business would have to pay were it to be deprived of those assets and have to replace them.

[127] Net book value is unlikely to differ materially to value to the business for these assets.

typically calculated by taking the value of trade receivables and inventory, less the value of trade payables.

3.144 The CMA requested data from Advanz on the value of trade payables, trade receivables and inventory for Liothyronine Tablets. Advanz was unable to provide data specific to Liothyronine Tablets in respect of trade receivables and trade payables.[128] Advanz did, however, provide data which could be used to estimate the share of receivables and payables that related to Liothyronine Tablet sales.[129] The CMA used this information to calculate the actual working capital balance associated with Liothyronine Tablets, as set out in the 2017 SO.

3.145 In the 2017 SO, the CMA:

(a) Allocated the receivables values provided by Advanz[130] to Liothyronine Tablets in proportion to the value of UK sales of Liothyronine Tablets relative to total group wide sales.

(b) Allocated the trade payables values provided by Advanz[131] to Liothyronine Tablets in proportion to the value of UK purchases of Liothyronine Tablets from the CMO relative to total group wide direct costs.

(c) Used the inventory balances specific to Liothyronine Tablets, which were provided by Advanz.[132]

3.146 In response to the 2017 SO, Advanz submitted that the approach applied to allocate receivables and payables to Liothyronine Tablets included an allocation error.[133] The primary reason for this was that the receivables and payables balances provided by Advanz were not global balances. Rather, the receivables and payables balances provided by Advanz were from subsidiaries of Advanz, namely Mercury Pharmaceuticals Ltd (receivables) and Amdipharm Ltd (payables).[134] Advanz proposed the following resolution to this 'allocation error':

[128] Document LIO1726, '*Liothyronine Data (2)'* states in note number 7 that '*Product specific receivables data for Liothyronine is not available*' and in note number 8 that '*Product specific payables data for Liothyronine is not available*'.
[129] Document LIO6284.82, '*FTI Report Evidence Item-40 - My Model*', 'Working capital - Tables' tab.'
[130] Document LIO1726, '*Liothyronine Data (2)'.*
[131] Document LIO1726, '*Liothyronine Data (2)'.*
[132] Document LIO1726, '*Liothyronine Data (2)*'.
[133] Document LIO6361.3, First FTI Report, paragraph 5.43.
[134] Document LIO6361.3, First FTI Report, paragraph 5.41, and document LIO6664, Advanz's response to question 5 of the CMA's s.26 notice dated 4 July 2018. Based on this information, the payables balance only related to Amdipharm from June 2014 onwards.

(a) Allocate the receivables values provided by Advanz to Liothyronine Tablets in proportion to the value of UK sales of Liothyronine Tablets relative to the total sales of Mercury Pharmaceuticals Ltd.[135]

(b) Allocate the trade payables values provided by Advanz to Liothyronine Tablets in proportion to the value of UK purchases of Liothyronine Tablets from the CMO relative to total direct costs of Amdipharm Ltd.[136]

(c) Continue to use the inventory balances specific to Liothyronine Tablets, which were provided by Advanz.[137]

3.147 On the basis that the receivables and payables balances provided by Advanz relate to subsidiaries and not the global working capital balances, the CMA agrees with the approach suggested by Advanz, set out at paragraph 3.146 above and has updated its analysis accordingly.[138]

3.148 Using Advanz's actual receivables balance is significantly favourable to Advanz. This is because the receivables balances resulting from a product sold at an excessive price do not represent an efficient level of capital employed in the business, since the high price reflects Advanz's pricing conduct rather than an actual cost and so inflates the level of receivables proportionately. Given the substantial upward trend in prices during the Infringement Period, the distorting impact of using actual receivables is greatest towards the end of the Infringement Period.

3.149 As the difference between prices charged and costs incurred in the later part of the Infringement Period was very high, including Advanz's actual working capital in the assessment as part of Advanz's capital base does not affect the outcome of the CMA's assessment.[139] The CMA has therefore concluded that, while Advanz's actual receivables balance represents an overestimate of the receivables balance associated with producing Liothyronine Tablets, it is not necessary to attempt to restate the working capital estimates to an efficient level, given that it would not change the CMA's overall conclusion that Advanz's prices were excessive during the Infringement Period.

3.150 The CMA has [✂].[140]

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[135] Document LIO6284.82, '*FTI Report Evidence Item-40 - My Model'*, 'Working capital – Tables' tab.
[136] Document LIO6284.82, '*FTI Report Evidence Item-40 - My Model'*, 'Working capital – Tables' tab.
[137] Document LIO1726, '*Liothyronine Data (2)*'.
[138] CMA Cost Plus assessment – 'Working capital' tab.
[139] Alternative approaches include linking the working capital to the estimated Cost Plus, i.e. assuming prices are set at Cost Plus or taking the price point at which prices first become excessive and using that price to derive the working capital allowance. Such approaches may be appropriate in other cases.
[140] Document LIO1526, *'Draft Finance Review on* [✂] *– May 2013'*, page 24.

i. Amortisation and depreciation

3.151 Depreciation and amortisation are the costs associated with spreading the costs of capital assets over their UELs. Accordingly, the value of the asset declines over time. Depreciation and amortisation charges are included in indirect and direct costs, respectively. Depreciation and amortisation also affect the value of the capital base used in calculating a reasonable rate of return for investors. The largest value capital item used in the supply of Liothyronine Tablets that potentially requires amortisation is the value of the Product Rights.

3.152 The evidence suggests that the value of the Product Rights did not amortise during the Infringement Period. The value of the Product Rights may amortise if competition becomes so intense that the recoverable amount is lower than the replacement cost,[141] or if a new drug is developed that makes Liothyronine Tablets redundant. Neither of these scenarios occurred during the Infringement Period. Therefore, for the purposes of the Cost Plus analysis, the CMA concludes that it is appropriate to assume that the value of the Product Rights was preserved from 2009 to 2017 and therefore that the Product Rights should not be amortised.

3.153 The CMA has therefore decided to include a constant value for the Product Rights of [✂] throughout the Infringement Period.

3.154 However, while the CMA considers this approach to the amortisation of Product Rights for the purpose of Cost Plus to be an appropriate and reliable methodology, as a precautionary cross-check, the CMA has also applied a sensitivity adopting different approaches to the amortisation of Product Rights.[142]

3.155 Depreciation of group tangible fixed assets is treated as an 'indirect cost', as these assets are shared across all drugs in Advanz's portfolio. The depreciation charge for tangible fixed assets in this case is small and does not have a material impact on the results.[143] Further, the assets are common, so the depreciation charge on these assets is a common cost and is therefore allocated to Liothyronine Tablets using sales volumes, alongside other common cost categories, as set out at paragraph 3.39 above.

[141] This would only occur under circumstances of intense competition, where prices fell to a level which did not include the full product rights – i.e. long-run incremental cost in a mature market, where firms have recovered their upfront costs of entry.

[142] The CMA applied two sensitivities on the amortisation profile covering (i) no amortisation and (ii) amortisation over 20 years from the start of the Infringement Period.

[143] Depreciation charge is £0.02 for each year of the Alleged Infringement Period. See Table A3.3 above.

II. Cost of capital

3.156 As set out in paragraph 3.61 above, the second input to determining a reasonable rate of return requires the CMA to establish the cost of capital, i.e. the average percentage return that debt and equity investors expect in return for providing funds to a company they have invested in. Allowing investors a profit in line with a ROCE estimate is based upon the principle that, under normal market conditions, profits are generated from the use of capital and are related to the level of risk taken. In applying the ROCE model, one assumes that sufficient profits need to be made to pay providers of capital a market-based return on their investments.

3.157 The CMA concludes that where firms, like Advanz, fund their investments through a combination of debt and equity finance, the WACC is the most appropriate figure to use for the rate of return expected by investors. It represents the average rate of return sought by debt and equity investors, and therefore represents the average cost of capital which can be applied to Advanz's capital employed, in order to measure ROCE.

3.158 The CMA considered WACC estimates from the Parties' internal documents. These ranged from [✂] to [✂]:

(a) While Advanz did not provide formal estimates of the cost of capital it uses as a business, it did state that a rate of [✂] was applied from at least 2010 onwards for internal project appraisals.[144]

(b) Globalview Advisors used a post-tax WACC of [✂] when valuing the intangible assets of Mercury Pharma Limited following the acquisition by Cinven in May 2013.[145]

(c) A Goldman Sachs presentation dated 4 September 2015 provided analysis of the potential financial impact of acquiring AMCo from Cinven.[146] The report estimated a range of different post-tax WACCs, with possible values between [✂].[147]

(d) EY estimated Advanz's post-tax WACC to be in the range of [✂] and [✂] and selected a value of [✂] for preparing its purchase price allocation report in September 2016.[148]

[144] Document LIO2589, Advanz's response to question 1 of the CMA's s.26 notice dated 27 February 2017.
[145] Document LIO1724, 'Mercury PPA Report.pdf', page 29.
[146] Document LIO1923, 'Document 2.pdf *Project Harmony – presentation'
[147] Document LIO1923, 'Document 2.pdf *Project Harmony – presentation', page 27–29.
[148] Document LIO4937, 'EY Report', Exhibit 15.

3.159 As explained in more detail in Annex 4, the CMA concludes that the cost of capital estimates from the Parties' internal documents are not suitable for an assessment of efficient capital costs. All of them were created in order to provide an assessment at a specific point in time and for a particular purpose. That makes them unsuitable for the purpose of estimating a WACC for the whole Infringement Period. They are also unsuitable for the following reasons:

(a) Advanz's [✂] cost of capital estimate represents a 'hurdle rate' that is likely to reflect a rate of return that management would hope to generate but this will not necessarily be the case. Management might use this higher 'hurdle rate' for project appraisals as a way of overcoming optimism bias.

(b) The cost of capital estimates used by Globalview Advisors and EY include a *'small company premium'* and a *'specific company premium'*.[149] This approach is not appropriate as there is no basis for it in the Capital Asset Pricing Model (CAPM), which is the model used by both reports.[150] Further, the Globalview Advisors and EY Report provide post-tax WACC estimates but the CMA considers that a pre-tax WACC is more appropriate for the purposes of an economic cost assessment.

(c) Goldman Sachs' WACC estimates are also presented as post-tax. While they do not suffer from the same methodological issues as the Globalview Advisors or EY Report assessments with respect to the inclusion of premia outside the CAPM, the CMA observes that, after adjusting the analysis to make it comparable with the CMA's pre-tax WACC, Goldman Sachs' WACC estimates fall towards the lower end of the CMA's WACC estimate range. Therefore, on a cautious basis, the CMA does not use them to assess efficient capital cost.

3.160 Given the wide range of WACC estimates evidenced from the Parties' internal documents and the inappropriateness of using those estimates for the purposes of an economic cost assessment for the reasons outlined above, the CMA has instead used market data to estimate a reasonable rate of return for Advanz that takes into account any potential changes in the cost of debt and equity over the course of the Infringement Period.

3.161 The CMA concludes that a 10% rate of return on capital employed is reasonable for its Cost Plus assessment in this case. However, as a cross-

[149] Document LIO1724, 'Mercury PPA Report.pdf.', page 28; document LIO4937, 'EY Report', pages 52-53.
[150] See Brealey, RA (1991), 'Principles of Corporate Finance', chapter 8

check, the CMA has also applied a 15% WACC (which is greater than the WACC submitted by Advanz (see Annex 4 for more detail)) as a sensitivity.[151]

III. Conclusions regarding the reasonable rate of return (the 'Plus')

Return on intangibles

3.162 As explained at paragraphs 3.152 and 3.153 above, in the CMA's Cost Plus calculation, it has been assumed that the value of the Product Rights is [✂] and that they do not amortise during the Infringement Period. A reasonable rate of return is then calculated by multiplying the WACC of 10% by the value of Advanz's intangible assets (that is its Product Rights) during the Infringement Period. Table A3.5 below sets out the value of intangible assets during the Infringement Period alongside the total return on the asset value and return per pack.

Table A3.5: Return on intangibles, as per CMA analysis of Advanz's costs

	2009	2010	2011	2012	2013	2014	2015	2016	2017
Intangible asset value £000s	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Return on intangibles £000s (10%)	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Return per pack £	**£0.67**	**£0.67**	**£0.63**	**£0.66**	**£0.63**	**£0.64**	**£0.63**	**£0.61**	**£0.74**

Source: CMA Cost Plus assessment – 'Annualised capital employed' and 'Cost stacks post reps' tabs.

Return on tangible fixed assets

3.163 As explained at paragraphs 3.138 to 3.142 above, tangible fixed assets have been allocated to Advanz in line with the number of packs sold and the CMA uses the book values for its asset value estimates. The return is then calculated by multiplying the WACC of 10% by the asset values during the Infringement Period. The return on tangible assets per pack is <£0.01 on average.

Return on working capital

3.164 As set out at paragraphs 3.143 to 3.150 above, the CMA has allocated working capital using an estimate of the actual working capital employed in providing

[151] HgCapital and Cinven, in contrast, submitted WACC estimates above 15% in their mid and upper case estimates. See document LIO6259, First HgCapital CRA Report, Table 6, and document LIO6331, First Cinven CRA Report, Tables 7 and 8.

Liothyronine Tablets during the Infringement Period. The analysis is based on information provided by Advanz.

3.165 The approach to working capital is very favourable to Advanz, as it allows a return on working capital which is significantly inflated by Advanz's pricing conduct. The approach materially increases the cost per pack. The effect is particularly pronounced towards the end of the Infringement Period as illustrated in Tables A3.6, A3.7 and Figure A3.2 below and further explained in paragraph 3.169 below.

Table A3.6: Return on working capital, as per CMA analysis of Advanz's costs

	2009	2010	2011	2012	2013	2014	2015	2016	2017
Net working capital £000s	662	685	1,166	1,326	1,839	2,755	4,545	7,248	6,734
Return on working capital £000s (10%)	66	68	117	133	184	276	455	725	393[152]
Return per pack £	**0.47**	**0.48**	**0.77**	**0.93**	**1.21**	**1.86**	**3.04**	**4.69**	**5.25**

Source: CMA Cost Plus assessment – 'Working capital' and 'Cost stacks post reps' tabs.

E. Conclusions regarding the CMA's Cost Plus analysis

3.166 The following section sets out the results of the CMA's analysis in relation to each of the three types of cost: direct costs, indirect costs and reasonable rate of return.

3.167 Total costs including the Plus element, are the sum of direct costs, indirect costs and the reasonable rate of return on capital. Table A3.7 below sets out the costs per pack in the Cost Plus analysis. Figure A3.2 shows the total costs graphically.

[152] Pro-rated by 7/12.

Table A3.7: Advanz's Cost Plus

	2009	2010	2011	2012	2013	2014	2015	2016	2017	Simple Average
Direct costs per unit (£)	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Indirect/ common costs per unit (£)	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Amortisation charge (£)	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Depreciation charge (£)	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Return on intangibles (£)	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Return on tangibles (£)	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Return on working capital (£)	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Total costs (£)	**2.08**	**2.10**	**3.12**	**2.75**	**3.99**	**5.11**	**5.63**	**9.87**	**9.78**	**4.94**

Source: CMA Cost Plus assessment – 'Cost stacks post reps' tab.

Figure A3.2: Advanz's Cost Plus (£)

[✂]

Source: CMA Cost Plus assessment – 'Charts' tab.

3.168 Table A3.7 and Figure A3.2 show that Advanz's Cost Plus ranges from £2.08 per pack to £9.87 per pack during the Infringement Period, with a simple average of £4.94 per pack.

3.169 As can be seen from both the table and figure above, the return on working capital inflates the Cost Plus numbers considerably towards the end of the Infringement Period. This is because the prices increased substantially throughout the Infringement Period, which in turn inflates the receivables balance in working capital. To illustrate this inflation: if the return on working capital were to be calculated by reference to the 2009 ASP throughout the Infringement Period rather than by reference to the price reflecting Advanz's ongoing conduct, total costs for the last three years of the Infringement Period would have been as follows: £3.04 for 2015, rather than £5.63 when using the 2015 ASP; £5.61 for 2016, rather than £9.87 when using the 2016 ASP; and £5.05 for 2017, rather than £9.78 when using the 2017 ASP.[153]

[153] CMA Cost Plus assessment – 'Working capital' tab.

3.170 However, while the effect of using Advanz's actual working capital balances artificially increases the Cost Plus estimate towards the end of the Infringement Period, the impact is not material for the overall assessment, given the significant and widening gap between prices and costs (see Figure A3.3 below).

F. Sensitivities to Cost Plus

3.171 In this section, the CMA applies a series of sensitivities to its Cost Plus analysis addressing representations made by the Parties. These serve as a cross-check to assess the robustness of the CMA's conclusions reached on the basis of Cost Plus.

I. Activity-based costing

3.172 As set out at paragraph 3.42 above in relation to common cost allocation, Advanz provided an activity-based costing ('**ABC**') model in response to the 2017 SO. The CMA has used an adjusted version of this model, in order to test the impact of using activity-based costing on its Cost Plus estimates. The sensitivity on common cost allocation has been carried out on a precautionary basis to recognise that there is no single valid approach to common cost allocation and that alternative methods can be appropriate where suitable information is available. In preparing its model, Advanz:

(a) Provided a detailed breakdown of its common costs. This was available from 2014 to 2017;[154]

(b) Cleaned the data:

(i) Costs which were reported as common, but which were irrelevant to the supply of Liothyronine Tablets in the UK, were removed. For example, costs that were specific to other countries.[155]

(ii) Costs which were reported as common, but which had already been included elsewhere in the cost assessment were removed – namely, dual sourcing costs, stock write-offs and expert support costs. This was to avoid double counting of these costs in Cost Plus.[156]

(c) Grouped costs into categories, having regard to the nature of the costs and associated activities.[157]

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[154] Document LIO6361.3, First FTI Report, paragraphs 8.18, 8.20 and 8.21; document LIO6284.82, '*FTI Report Evidence Item-40 - My Model'* – 'Indirect costs' tabs.
[155] Document LIO6361.3, First FTI Report, paragraphs 8.18, 8.22 to 8.23; document LIO6284.82, '*FTI Report Evidence Item-40 - My Model'* – 'Indirect costs' tabs.
[156] Document LIO6361.3, First FTI Report, paragraphs 8.18 and 8.24 to 8.26 and document LIO6284.82, *'FTI Report Evidence Item-40 - My Model'* – 'Indirect costs' tabs.
[157] Document LIO6361.3, First FTI Report, paragraphs 8.18, 8.27 and 8.28 and document LIO6284.82, *'FTI Report Evidence Item-40 - My Model'* – 'Indirect costs' tabs.

(d) Identified a cost driver for each category and calculated the percentage driver that should be used.[158]

(e) Allocated the costs in each category using the drivers calculated.[159]

3.173 A summary of Advanz's cost categories and selected cost drivers is set out in Table A3.8 below.

Table A3.8: Advanz's cost categories and cost drivers

Cost category	Amount (£m) (2016)	Driver	% Driver
Drug safety and Quality costs	5.4	Volume - Molecule	[✂]
Medical Affairs	3.6	Volume - Molecule	[✂]
Technical, regulatory and specific	1.4	Complexity	[✂]
Executive costs	2.3	Volume - Molecule	[✂]
Supply chain management	2.1	Volume - packs	[✂]
Procurement	0.1	Volume - packs	[✂]
General Corporate costs	14.9	EPMU	Calculated
UK-specific costs	5.4	EPMU	Calculated
Finance	2.6	EPMU	Calculated
Miscellaneous	0.0	EPMU	Calculated

Notes:

Advanz has made several adjustments to the treatment of indirect costs. The most material changes are as follows:

(1) Changed the cost driver for 'Drug safety and quality', from complexity to molecule; and relatedly, applied a complexity cost driver to 'Technical, regulatory and specific' costs, which had initially been allocated by molecule.

(2) Removed internal Advanz staff costs of £4,756,616 for the period 2014–2017 from the 'Technical, regulatory and specific' cost category that was related to dual sourcing activity to avoid double-counting with the supplier relationship intangible asset. As explained in paragraphs 3.72–3.76, the CMA does not consider it appropriate to recognise a supplier relationship intangible. Instead, the CMA retains the 'internal staff costs' within the 'Technical, regulatory and specific' cost category and allocates a proportion of these group level costs to Liothyronine Tablets. Under this approach, the CMA recognises a 'notional expense' for any Liothyronine Tablets supplier relationship related costs as an 'indirect cost'.

Source: Document LIO12049, '*FTI Report Evidence Item-59 – My Updated Model*', 'Indirect costs – Tables' tab, Table 8.3.

[158] Document LIO6361.3, First FTI Report, paragraphs 8.18, 8.27 and 8.28 and document LIO6284.82, *'FTI Report Evidence Item-40 - My Model'* – 'Indirect costs' tabs.

[159] Document LIO6361.3, First FTI Report, Table 8-5; document LIO6284.82, *'FTI Report Evidence Item-40 - My Model'* – 'Indirect costs' tabs.

a. Differences in approach between the CMA and Advanz

3.174 The only difference in approach between the CMA's ABC sensitivity and Advanz's ABC model relates to the allocation of costs accounted for in the 'Technical, regulatory and specific' cost category. The differences are as follows:

(a) On a net basis, the CMA recognises a higher amount of costs in the 'Technical, regulatory and specific' cost category than Advanz. This is because:

(i) The CMA removes [✂] of BSV costs from this cost category and recognises the same amount as a 'direct' cost in the years when those costs were actually incurred.

(ii) Advanz removes £4,757,000 of internal employee staff costs related to dual sourcing to avoid double-counting with the supplier relationship intangible asset. As explained in paragraph 3.74 above, the CMA does not recognise such an intangible asset and therefore does not remove these costs, as there is no risk of double-counting.

(b) The CMA applies a [✂] percentage driver to allocate costs from that cost category to Liothyronine Tablets, whereas Advanz uses a [✂] percentage driver.

3.175 In the remainder of this section, the CMA explains Advanz's approach to choosing the cost drivers and then explains why its choice of percentage driver is more appropriate given the available information and the treatment adopted by the CMA in other parts of its Cost Plus assessment.

b. Cost drivers

3.176 The CMA reviewed the grouping of the costs into categories and the choice of drivers. The CMA notes that Advanz described its activity-based costing approach as follows:

> '*[Advanz] does not have an ABC costing system and to develop one would be costly, time consuming and require time and motion studies. Therefore, it is necessary to adopt a more pragmatic approach, considering the data available*.'[160]

3.177 The CMA does not consider Advanz's grouping of costs to be unreasonable but notes that limited information has been provided to support the chosen drivers.

[160] Document LIO6361.3, First FTI Report, paragraph 8.7.

3.178 The key driver in terms of materiality is the complexity driver. The complexity driver was initially used to allocate 'Drug safety and quality' costs (but Advanz subsequently submitted that the complexity driver should be applied to the 'Technical, specific and regulatory' cost category). Initially, the rationale given by Advanz for allocating drug safety and quality costs on the basis of complexity was:

> '*I understand that certain medical, technical and regulatory costs will vary between drugs depending on the complexity of production and supply. These costs mostly relate to staff costs and therefore are reflective of the time required for dealing with quality assurance, technical and regulatory issues*.'[161]

3.179 The CMA would ordinarily expect that robust evidence would be provided to support the chosen cost drivers, in order to demonstrate compliance with the cost causality principle. For example, for the complexity driver, time sheets might have been expected, evidencing that staff did indeed spend more time on more complex drugs. The CMA requested more detail of the rationale for allocating drug safety and quality costs on the basis of complexity. Advanz confirmed that the evidence for its approach was limited to discussions with management.[162]

3.180 In response to the 2019 SSO, Advanz carried out a review of the 'Technical, regulatory and specific' cost category and identified costs relating to 'additional stability testing' (i.e. BSV costs). Advanz argued that, as the BSV costs were directly attributable to Liothyronine Tablets, and as Liothyronine Tablets are a 'complex' drug, the costs within that category were likely to be driven by complexity. Advanz updated its model to allocate the 'Technical, regulatory and specific' cost category by reference to the complexity driver.

3.181 Although no evidence was provided to show that Liothyronine Tablets were more difficult to manage than Advanz's other hard to make drugs, the CMA acknowledges that it may be reasonable to assume that more complex drugs require more staff time.

3.182 The CMA therefore adopts Advanz's chosen drivers for the purposes of its sensitivity.

[161] Document LIO6361.3, First FTI Report, paragraph 8.33.

[162] Document LIO6664, Advanz's response to question 13 of the CMA's s.26 notice dated 7 June 2018.

c. Percentage drivers

3.183 Turning to the percentage drivers used, the CMA agrees with Advanz's percentage drivers for '*volume-packs'* and '*volume-molecules'*.

3.184 As explained in paragraph 3.180 above, Advanz carried out a review of the 'Technical, regulatory and specific' cost category and identified BSV costs that were directly attributable to Liothyronine Tablets. As the proportion of BSV costs within that category were high in some years (e.g. 2016), Advanz argues that this provides support for a [✂] percentage driver for that cost category, to be applied for every year of the Infringement Period. However, in the CMA's view, the [✂] driver used for drug complexity is unlikely to be robust because:

(a) Advanz has [✂] drugs in its portfolio.[163,164] Liothyronine Tablets make up between [✂] and [✂] of sales by volume of packs. It seems highly unlikely that one drug out of [✂] drugs representing such a small proportion of pack volumes should account for [✂] of costs for technical and regulatory costs.

(b) The EY Report shows that, of Advanz's [✂] drugs, [✂] were hard to make[165] It therefore seems unlikely that Liothyronine Tablets, as just one of [✂] hard to make drugs, account for [✂] of the costs driven by complexity.[166]

(c) The [✂] percentage driver is based on evidence that is only partially accurate; the CMA's review found that only [✂] of the [✂] of the costs identified by Advanz actually related to Liothyronine Tablets during the Infringement Period.[167] Although the identified costs were lower than initially proposed, and Advanz changed approach and now applies the complexity driver to a different cost category – technical and regulatory costs – it makes no adjustment to the percentage driver, which remains at [✂].

(d) As explained in paragraph 3.21 above, the BSV costs identified by Advanz that purport to show that Liothyronine Tablets attracted more costs than Advanz's other drugs were one-off costs and were not incurred uniformly during the Infringement Period. There was no BSV activity in 2009, 2010 or 2012. The majority of the identifiable costs were incurred in one year, 2016. While

[163] See document LIO6932, Advanz's response to question 1 of Annex 1 of the CMA's s.26 notice dated 20 July 2018, and document LIO6933, Advanz's '*Annex 1 – Forest – loss making contribution by SKU*', which has 285 drugs listed.

[164] The CMA observes that an alternative approach to allocating common costs would be to use [✂] i.e. use volume of drugs supplied, rather than volume of packs, which is [✂] for Advanz's supply of Liothyronine Tablets. This is lower than the aggregate driver used in the adjusted ABC analysis of [✂]. The results are therefore also robust to this allocation approach.

[165] Document LIO4937, EY Report, Exhibit 11, page 2.

[166] Put another way, staff working on technical and regulatory matters would, by corollary, be expected to spend eight times longer on Liothyronine Tablets than on any of Advanz's other 'hard to make' drugs.

[167] Document LIO7790.5, '*FTI Report Evidence Item-47 - BSV costs 2014 - 2017.ods*'.

Liothyronine Tablets specific costs were high in 2016, the proportion of costs attributable to Liothyronine Tablets in the other years of the Infringement Period were low.[168] The CMA does not consider that the evidence provided by Advanz supports the view that Liothyronine Tablets disproportionately drove technical and regulatory activity relative to its [✂] other products, in each year of the Infringement Period.

(e) Advanz's review suggests that the costs included in the 'Technical, regulatory and specific' cost category – if similar to the identified Liothyronine Tablets specific costs – would likely include costs that are directly attributable to Advanz's other products. Given that the CMA has treated those Liothyronine Tablets specific costs as direct costs and removed the same from the 'Technical, regulatory and specific' cost category, it may be that some, if not most, of the remaining costs in that category relate to Advanz's other products. Applying Advanz's approach would lead to an overstatement of that cost category and 'indirect costs' as a whole. Even applying a [✂] driver would likely overstate indirect costs if most of those remaining costs were attributable to Advanz's other products.

(f) Advanz's [✂] driver is based on the know-how value of Liothyronine Tablets[169] as a proportion of the total know-how valuation in the EY Report. It is not clear why there should be a direct link between the relative value of know-how and the amount of time spent on technical and regulatory activity related to a particular drug. Further, the CMA does not consider that the EY Report provides a valuation of know-how that is suitable for the purposes of an economic cost assessment, as explained at paragraph 3.136 above.

3.185 In the absence of robust information from Advanz on the amount of staff time spent on technical and regulatory activity relating to Liothyronine Tablets, the CMA concludes that a pragmatic and reasonable approach is to apply a driver of [✂], given that there are [✂] hard to make drugs in Advanz's portfolio.

3.186 In any event, the CMA's treatment of BSV costs as a 'direct cost' and the application of a [✂] percentage driver results in an overall allocation of the 'Technical, regulatory and specific' cost category that is similar to Advanz's ABC allocation of [✂]. Comparing like for like, the CMA's sensitised Cost Plus allocates, on average [✂] of the 'Technical, regulatory and specific' costs to Liothyronine Tablets for the period 2014–2017; and [✂] for the period 2009–

[168] Even on the basis of Advanz's analysis (which the CMA does not accept) the additional stability testing identified by Advanz accounts for less than [✂] of the 'Technical, regulatory and specific' costs in 2014, less than [✂] in 2015 and less [✂] in 2017; and none of the costs in 2009, 2010 or 2012, as no BSV activity took place in those years. The average over the period 2014–2017 is distorted upwards by the high, one-off BSV costs in 2016 that accounted for approximately 23% of the costs accounted for in the 'Technical, regulatory and specific' cost category.

[169] Following the application of Advanz's factor of [✂], which is applied to the EY valuation.

2013.[170] The CMA's approach is very favourable to the Parties, as it assumes that Liothyronine Tablets drive significantly more of the costs in that category than Advanz's other hard to make drugs while also assuming that no staff time is spent on Advanz's easy to make drugs.

II. Product Rights

3.187 As set out at paragraphs 3.152 and 3.153 above, the upper end of Teva's entry cost estimate has been used in the CMA's Product Rights valuation and the Product Rights have not been depreciated during the Infringement Period.

3.188 The CMA considers that its approach to valuing Product Rights based on the entry costs of successful entrants is appropriate and does not require change. However, in response to the Parties' representations, by way of a sensitivity, as a cross-check, the CMA has also valued the Product Rights for Liothyronine Tablets based on an alternative methodology which takes account of a potential risk of failure to derive an upper-end valuation of Product Rights. The CMA has considered the effect of amortisation by applying two different amortisation profiles to this upper-end Product Rights valuation.

a. Probability adjusted ex ante replacement cost to account for a possible risk of failure

3.189 HgCapital and Cinven submit that the use of Teva's entry costs understates the *ex ante* replacement cost of the Product Rights given that there was a material risk of failure in obtaining the Product Rights.

3.190 Instead of relying on the entry costs of actual entrants, Cinven and Hg Capital suggest multiplying the 'typical' development costs of actual and potential entrants by a factor to reflect the number of attempts required in order to provide a reasonably high likelihood of success. They claim that there were 13 attempts at entry of which only two were successful, which they argue would indicate a 15% probability of success.[171,172] They argue that the cost

[170] This is the sum of the CMA's BSV cost allocation with the [✂] allocation the CMA applied to 'Technical, regulatory and specific' cost category. The CMA's total allocation percentage as a proportion of the total costs accounted for that cost category in Advanz's model, to ensure comparability of percentage drivers.
[171] Document LIO6331, First Cinven CRA Report, paragraph 88-89; document LIO6258, HgCapital RSO, paragraph 110(f); document LIO6259, First HgCapital CRA Report, paragraph 97 and 102.
[172] In response to the 2019 SSO, Cinven and HgCapital argued that 10 firms had made a 'realistic attempt': Teva; Morningside; [PE2]; [PE3]; [PE12]; [PE1]; [PE10]; [PE13]; Focus; and Primegen. As only two of these have been successful, they estimated a probability of success of 20%. Document LIO7794, Second Cinven CRA Report, paragraph 93; Document LIO7801, Second HgCapital CRA Report, paragraph 103. As set out in paragraph 3.197 below, the CMA considers that only six firms have made a realistic attempt to enter the market, i.e. the first five included in Cinven and HgCapital's list and [PE16], which has incurred substantial costs and applied for an MA. The other firms in the list have incurred limited or no costs, nor have they undertaken the required scientific work to secure an MA or they have since been acquired by Advanz.

estimates submitted to the CMA by potential and actual entrants appear incomplete, with categories of costs being excluded,[173] and suggest using a 'typical' development cost for this analysis at the upper end of the range, of £600,000.[174] Cinven and HgCapital apply a multiple of 10 and 15 respectively to the assumed £600,000 development cost, resulting in a valuation of £6m-£9m.[175,176]

3.191 In response to the Parties' representations, the CMA has applied a sensitivity to the Product Rights valuation to factor in a possible risk of failure (that is the risk that a potential entrant requires more than one attempt) and to reflect uncertainty around the level of investment required to obtain the Product Rights, leading to an upper end valuation of £2.1 million.[177] The CMA's sensitivity again greatly favours the Parties, in that:

(a) the assumptions underpinning the CMA's probabilistic model bias the sensitivity estimate upwards; and

(b) the inputs into the model adopt the most conservative approach by using:

(i) the upper end of entrants' cost estimates (e.g. Teva and [PE1] entry costs), which biases the average cost of development upwards; and

(ii) the highest risk of failure or lowest probability of success (i.e. 33% probability of success assuming that the two current entry attempts by [PE1] and [PE16] will result in failure).

Both factors bias the sensitivity estimate upwards.[178]

b. Methodological approach to calculating the CMA's ex ante replacement cost sensitivity

3.192 The Parties have proposed a model of entry (a 'Bernoulli trial'), by which the development process is treated as a random experiment with two possible outcomes – 'success' or 'failure' – in which the probability of success is the same every time the experiment is conducted and each attempt is treated as

[173] Document LIO6331, First Cinven CRA Report, footnote 71; document LIO6259, First HgCapital CRA Report, footnote 68. See also document LIO6331, First Cinven CRA Report, footnotes 69-73 and document LIO6259, First HgCapital CRA Report, footnotes 72-73, which detail other categories of costs which the Parties believe are missing from the entry cost estimates provided to the CMA.
[174] Document LIO6331, First Cinven CRA Report, paragraphs 88 and 90; document LIO6259, First HgCapital CRA Report, paragraph 99.
[175] Document LIO6331, First Cinven CRA Report, paragraphs 89 and 90; document LIO6259, First HgCapital CRA Report, paragraph 103.
[176] In response to 2019 SSO, CRA estimate a Product Rights valuation of [✂].
[177] The CMA's sensitised Product Rights valuation has increased from £1.2 million (as per the 2019 and 2020 SSO) to £2.1 million in the light of new information from actual and potential entrants.
[178] See paragraph 3.209 below for more detail.

independent and identical.[179] In the Parties' model, the *ex ante* replacement cost is the expected value of this Bernoulli trial and is calculated by dividing the average cost of entry by the probability of success.

3.193 This approach treats the development process as an entirely random process when, in reality, the outcome of the development process is not probabilistic in nature but dependent on the commercial and financial commitment of the firms undertaking the development process. The Parties' model has several limitations and is based on a number of unrealistic assumptions:

(a) The Parties consider that 13 firms have made an 'attempt' to enter the market for Liothyronine Tablets but do not define what constitutes an attempt for the purposes of their analysis. The Parties include firms in their entry analysis that have not incurred any costs at all to develop Liothyronine Tablets.[180] As explained in paragraphs 3.198 to 3.199 below, this is not an appropriate basis on which to carry out a risk of failure analysis.

(b) The probability of success is the same for each entry attempt when, in practice, entrants would benefit from previous attempts and the probability of success would increase with each successive attempt.[181]

(c) The average cost is the same for each entry attempt when, in practice, entrants would benefit from previous attempts, and the cost of each successive attempt would reduce accordingly.[182]

(d) All firms have the same probability of success when, in practice, the quality and seriousness of the entry attempts vary significantly between firms; not all entry attempts are equal.[183]

(e) All firms are willing to a pay a premium (i.e. the *ex ante* replacement cost) to have a reasonably high likelihood of entry rather than developing the product internally at a lower cost but with the risk that the development might not succeed. This assumes that all firms have the same risk profiles and employ the same business strategy when in practice, pharmaceutical companies have different business models: firms that have research and development expertise and have prior experience of bringing new products to market are

[179] Document LIO6331, First Cinven CRA Report, paragraphs 84-90; document LIO6259, First HgCapital CRA Report, paragraphs 98 and 104.
[180] See paragraph 3.197 below for further detailed analysis.
[181] If a firm learns from its first attempt, it is more likely to be successful with its second attempt than the first attempt.
[182] A firm is not likely to start their second attempt with a blank slate but rather to build on data and experience from the first attempt. Thus, the 'average cost' of the second attempt is likely be lower than the first attempt.
[183] [✂]

more likely to develop the product internally at a lower cost than those firms that have less experience or pay to acquire MAs.

(f) The entry costs of all potential entrants were incurred reasonably and efficiently, even if those costs exceed the entry costs of actual, successful entrants by a material amount.

3.194 Despite the limitations set out above, which are likely to overstate the resulting figure/product rights value, for the purposes of the sensitivity the CMA has adopted a similar probabilistic model in order to estimate an '*ex ante replacement cost*'. In the absence of good quality information, the CMA has also had to treat each entry attempt as identical and independent. However, the CMA does not consider that the Parties' approach to identifying what constitutes an entry attempt is appropriate. The CMA considers that there is a need to differentiate between entry attempts that are realistic and those that are not. Otherwise 'unrealistic attempts' would by their very nature be regarded as 'failures' which would then distort and overstate the risks associated with developing Liothyronine Tablets. The CMA considers that an MA application is a reasonable threshold by which to determine whether a firm has made a realistic attempt to enter the market. The evidence from potential and actual entrants supports the CMA's choice of threshold.[184]

c. The CMA's *ex ante* replacement cost estimate

3.195 There are two inputs into the CMA's sensitivity estimate:

(a) The probability of success; and

(b) The cost of entry (or 'typical' development cost).

Probability of success

3.196 To estimate the probability of success, the CMA has had to determine:

(a) what actions by potential entrants amount to a realistic attempt to enter the market; and

(b) whether such an attempt has succeeded or failed.

3.197 The CMA collected evidence from 16 firms which had contacted the MHRA in relation to Liothyronine Tablets prior to the end of the Infringement Period, or which the CMA otherwise identified had commenced development work. Of these 16 firms, the CMA found that only six firms had applied for an MA and only those firms had incurred significant costs to develop the know-how

[184] See paragraph 3.199 below for more detail.

required to manufacture and/or supply Liothyronine Tablets in the UK. These firms were: Teva, Morningside, [PE2], [PE3], [PE1] and [PE16].[185] In the CMA's view, none of the other firms had made a realistic attempt to enter the market for the following reasons:

(a) Four firms told the CMA that they had no intention to apply for an MA for the manufacture and/or supply of Liothyronine Tablets in the UK:

(i) [PE17];[186]

(ii) [PE15];[187]

(iii) [PE19];[188] and

(iv) [PE14].[189]

(b) Four firms submitted that they had begun early development work but terminated development before incurring substantial costs or undertaking the required scientific work to secure an MA:

(i) [PE18] – incurred costs of [✂] prior to terminating development. It only produced tablets on a laboratory scale and did not produce '*regulatory stability batches*'.[190]

(ii) [PE10]/[PE20] – based on the responses from [PE10] and [PE20], the CMA understands that only [✂] of costs were incurred in developing Liothyronine Tablets before the project was terminated. [PE20] had initially started the project to develop generic liothyronine tablets for the UK when it was part of [PE10]. [✂]. [PE10] confirmed that the cost estimate of [✂][191] submitted to the CMA in response to an earlier information request related to [✂].[192,193,194]

[185] Morningside, [PE16] and [PE1], in addition to developing 20mcg strength attempted to develop Liothyronine Tablets for other strengths. However, as these strengths were different to the originator product under consideration (i.e. 20mcg product), the related costs of developing the other strengths are not relevant for the CMA's assessment and have been excluded from the entry cost estimate. [✂]

[186] Document LIO6936, [PE17]'s response to the CMA's s.26 notice dated 25 July 2018.

[187] Document LIO6536, [PE15]'s response to the CMA's s.26 notice dated 7 June 2018.

[188] Document LIO6958, [PE19]'s response to the CMA's s.26 notice dated 25 July 2018.

[189] Document LIO6581, [PE14]'s response to s.26 notice dated 7 June 2018.

[190] Document LIO6603.1, [PE18]'s response to s.26 notice dated 8 June 2018.

[191] Document LIO6578, [PE10]'s response to the CMA's s.26 notice dated 7 June 2018.

[192] Document LIO12169, [PE10]'s response to the CMA's s.26 notice dated 24 February 2021.

[193] Document LIO12092, [PE20] UK's response to the CMA's s.26 notice dated 30 September 2020.

[194] [PE10] submitted that it was not able to find records of any other studies relating to liothyronine being undertaken by [PE10]. This indicates that [PE20] incurred no or only negligible costs in connection with its Liothyronine Tablets development project while under [PE10] ownership. [✂], [PE20] took forward the Liothyronine Tablets development project but terminated it after incurring costs of [✂]. [PE20] did not undertake any stability testing or bioequivalence studies either.

(iii) [PE12] – did not submit any cost information but confirmed that it had not undertaken any stability testing or bioequivalence studies.[195]

(iv) Focus Pharmaceuticals – incurred estimated costs of €150,000 but the project was abandoned at an early stage following its acquisition by Advanz.[196]

(c) One firm told the CMA that it had incurred no costs to date as it had not yet begun the development of Liothyronine Tablets: [PE13].[197]

(d) One firm, Primegen, was acquired by Advanz in 2014, and had not, at the time of the CMA's latest request to the MHRA, applied for an MA for 20mcg Liothyronine Tablets in the UK.[198] Its development project was not aimed specifically at the UK market.[199]

3.198 Based on the evidence from these 10 firms, the CMA does not consider it appropriate to adopt the Parties' approach of including every single firm that has ever expressed an interest in the Liothyronine Tablets market as a relevant entry attempt. This is not a sensible basis to estimate the 'probability of success'. Otherwise, the model assumptions would place the same weight on potential entrants that have incurred limited or zero costs or have only undertaken limited scientific work to develop Liothyronine Tablets as on those potential entrants that have spent considerable time and effort to develop Liothyronine Tablets and incurred significant costs in the process. It is self-evident that firms that have incurred no or limited costs or not carried out the required scientific work would not be able to secure an MA for Liothyronine Tablets and/or enter the UK market.

3.199 Instead of adopting the Parties' speculative approach, the CMA has modelled the replacement cost on the basis that only firms that have applied for an MA for Liothyronine Tablets equivalent to Advanz's product (i.e. 20mcg Liothyronine Tablets) have made a 'realistic attempt' to enter the market. The CMA considers that this threshold is appropriate for the following reasons:

(a) Firms that have not applied for an MA have not undertaken one of the necessary steps to manufacture and/or supply Liothyronine Tablets in the UK.

(b) The evidence shows that firms that have not applied for an MA have neither incurred significant costs to develop Liothyronine Tablets nor undertaken the required research and development required to prepare an MA application.

[195] Document LIO3842, [PE12]'s response to the CMA's s.26 notice dated 13 July 2017; Document LIO12083, [PE12]'s responses to the CMA's s.26 notice dated 30 September 2020.
[196] Document LIO3980, Advanz's response the CMA's s.26 notice dated 25 July 2017.
[197] Document LIO12101, [PE13]' response to the CMA's s.26 notice dated 25 September 2020.
[198] Document LIO12167, MHRA's response to the CMA's s.26 response dated 18 February 2021.
[199] Document LIO3980, Advanz's response to the CMA's s.26 notice dated 25 July 2017.

Without having undertaken any of these steps, it cannot be reasonable to consider that these firms have made a realistic attempt to enter the market.

(c) It is a verifiable and objective threshold by which to determine the seriousness of an entry attempt.

3.200 On this basis, the CMA uses the entry cost information of the six firms that have applied for an MA for the supply of 20mcg Liothyronine Tablets in its risk of failure estimation. In the CMA's view, the other 10 firms have not made a realistic attempt to enter the market.[200]

3.201 On the basis of the evidence that shows that all potential and actual entrants have made only one MA application, the CMA concludes that it is appropriate to treat each firm's entry attempt as a single attempt.[201]

3.202 Of the six firms that have applied for an MA and have been included in the risk of failure analysis, only Teva and Morningside have entered successfully; [PE2] and [PE3] have withdrawn their applications; and the MHRA's decision is still pending for [PE1] and [PE16].[202] This means that the risk of failure is 50% (2 out of 4), based on actual confirmed MHRA decisions; or 33% if it is assumed that [PE1] and [PE16] both fail with their MA application; or 66% if it is assumed that [PE1] and [PE16] both succeed with their MA applications.

Cost of entry

3.203 In order to determine the 'typical' development cost, the CMA has taken an average of the costs incurred by the six firms that have made a realistic attempt to enter the market. The Parties have argued that:

(a) Firms' entry cost estimates are understated;

(b) Teva's entry costs should be used as the 'typical' development cost; and

(c) Forecast costs should be added to entry cost estimates for those firms that have MA applications pending.

3.204 With respect to the Parties' first argument, the CMA has collected updated cost information to arrive at a comprehensive and reliable estimate of entrants' costs. Of the six firms included in the CMA's risk of failure assessment, the CMA

[200] [✂]. (See document LIO7831, MHRA's response to the CMA's s.26 notice dated 12 August 2019; document LIO12167, MHRA's response to the CMA's s.26 notice dated 18 February 2021) [✂].
[201] Although the CMA initially understood that Morningside had made two separate attempts to enter the market, further evidence received from Morningside shows that the work it undertook amounted to a single attempt.
[202] No decision about [PE1] and [PE16]'s MA applications had been taken at the time of the MHRA's response of 3 March 2021 to the CMA's most recent information request. Document LIO12167, MHRA's response to the CMA's s.26 notice dated 18 February 2021.

notes that there is only a degree of uncertainty around Teva and [PE1]'s entry costs estimate:[203]

(a) As explained in paragraph 3.117 above, Teva submitted an entry cost estimate range of [✂] to [<£1 million]. The CMA adopts a cautious approach and uses the upper end estimate of Teva's range for the purposes of the Product Rights valuation for Cost Plus and the Product Rights sensitivity. This approach is very favourable to the Parties.

(b) [✂].[204] [✂]:

(i) [✂].[205]

(ii) [✂].[206]

(iii) [✂].[207] [✂].

3.205 With respect to the Parties' second argument, the CMA does not consider that it is appropriate to use Teva's entry costs as the basis of 'typical' development costs, as Teva entered successfully having incurred those costs. If other firms had spent as much as Teva, the implied success rate might be higher; that is, the more a firm spends in development, the more likely it will succeed. The CMA therefore considers that it is more appropriate to use an average of actual and potential entrants' costs.

3.206 With respect to the Parties' third argument, the CMA treats those firms that have pending MA applications as 'failed' attempts. It would be inappropriate to include forecast expenditure while also treating the attempts as 'failed', as firms that spend more money are more likely to succeed with their entry attempt.

d. CMA's sensitivity results

3.207 Table A3.9 provides a breakdown of the evidence of third-party entry costs. The cost information relating to Teva, Morningside, [PE2][208] and [PE3][209] is complete and final, as these firms have either entered successfully or terminated their development. However, [PE16][210] and [PE1][211] have ongoing development projects and there is no certainty on the likelihood or level of costs that may be incurred in future (though, as set out above, both have told the

[203] See Table A3.9 below for more detail.
[204] [✂].
[205] Document LIO3324, [PE1]'s '*47278641_1_Annex 1.PPTX*'.
[206] Document LIO3322, [PE1]'s '*47278648_1_Annex 3.PPTX*'.
[207] [✂].
[208] See document LIO12164, [PE2]' response to the CMA's s.26 notice dated 24 February 2021; document LIO12165, [PE2]' '*Copy of Liothyronine Expenses*'.
[209] See document LIO2206, [PE3]'s response to the CMA's s.26 notice dated 25 January 2017.
[210] See document LIO12178, [PE16]'s response to the CMA's s.26 notice dated 24 February 2021.
[211] See document LIO12170; [PE1]'s response to the CMA's s.26 notice dated 24 February 2021.

CMA that they do not expect to have to spend any further money on their respective development projects).

3.208 Based on the available information, the average cost of entry is [✂][212] and the implied probability of success is 50% (2 out of 4), based on actual confirmed MHRA decisions;[213] or 33% if [PE1] and [PE16] are assumed to fail with their MA applications; or 67% if [PE1] and [PE16] succeed with their MA applications. In the first case, based on verifiable evidence, the implied *ex ante* replacement cost is [✂]. In the second scenario, the implied *ex ante* replacement cost is [✂]. In the third scenario, the implied *ex ante* replacement cost is [✂]. Accordingly, the CMA's *ex ante* replacement cost estimates range from [✂].

Table A3.9: Summary of entry attempts outcomes and costs

[✂]

Source: CMA analysis of entrants' s.26 responses

3.209 The assumptions underpinning the CMA's model err in the Parties' favour and upwardly bias the CMA's *ex ante* replacement cost estimate, leading to a likely significant overstatement of the CMA's Product Rights valuation. In particular, the model assumes:

(a) **The cost of entry is the same for each attempt** whereas in fact the entry costs of each subsequent entry attempt are likely to be less costly. A firm is not likely to start its second attempt with a blank slate but rather to build on data and experience from the first attempt. [PE2] submitted that the cost of a second MA application would be lower than the first MA application cost, as it would be able to '*utilise data already gathered from the initial submission'* and that it would not be '*starting from scratch'*. Thus, the 'average cost' of the second attempt is likely to be lower than that of the first attempt.

(b) **The probability of success is the same for each attempt (33%)** whereas the probability of success would likely increase with each successive attempt. A firm would learn from its first attempt and as a result, would be more likely to be successful with its second attempt.

[212] If the CMA had adopted the lower end of Teva's entry cost range of [✂], the average cost of entry would fall to [✂]. This would reduce the CMA's ex ante replacement cost which would range from [✂] to [✂], with a midpoint of [✂]. Similarly, if the CMA did not apply an uplift for [PE1]'s 'missing costs' and used the relevant reported costs of [✂], the average cost of entry would fall to [✂]. This would reduce the CMA's ex ante replacement cost which would range from [✂] to [✂], with a midpoint of [✂]. If the CMA had used the lower end estimate for Teva and [PE1], the average cost of entry would fall to [✂]. This would reduce the CMA's ex ante replacement cost which would range from [✂] to [✂], with a midpoint of [✂].

[213] Or three out of six if one of [PE1] or [PE16] succeed with their entry attempt.

(c) **The success rate of 33% is based on the assumption that [PE1] and [PE16] will fail with their respective entry attempts** whereas no decision has yet been made about their MA applications. In order to provide an upper bound, the CMA has adopted a cautious approach and assumed a success rate of 33% contingent on two further failed attempts. It is no less likely that both **[PE1]** and **[PE16]** are granted an MA. If all other assumptions remain the same (i.e. the CMA still applies assumptions a), b) and d)), the impact of the CMA's cautious approach to probability of success is at least £0.7 million; and potentially as much as £1 million. This assumption again errs in the Parties' favour.

(d) **The CMA adopts the upper end of entrants' entry cost estimates** (i.e. Teva and [PE1]'s entry cost estimates), which biases the average cost of entry upwards. This, in turn, biases the CMA's *ex ante* replacement cost upwards. If all other assumptions remain the same (i.e. the CMA still applies assumptions a) to c)), the impact of the CMA's cautious approach with respect to entry costs is £0.2 million. This assumption again is favourable to the Parties.

3.210 The cumulative application of these assumptions therefore likely overestimates the *ex ante* replacement cost significantly. A more realistic approach would likely result in a significant reduction in the *ex ante* replacement cost valuation and would more likely reflect the efficient cost of developing Liothyronine Tablets. However, the CMA did not consider it appropriate to apply more real-world assumptions, given the lack of reliable evidence from actual and potential entrants. In any event, any model would likely only estimate the costs and risks associated with investment. Given these uncertainties, the CMA has adopted the Parties' modelling assumptions in order to arrive at an upper-end *ex ante* replacement cost, albeit one that is likely to be overstated. The sensitised replacement costs serves as a cross-check to the CMA's upper-end replacement cost valuation of [✂] and to test the results obtained from the CMA's Cost Plus assessment.

3.211 The Parties have proposed further adjustments to the probability adjusted *ex ante* replacement cost, namely:

(a) Risk aversion: risk averse investors would value Advanz's Product Rights higher than the CMA's *ex ante* replacement cost, as they would require 100% certainty of entry.[214]

[214] Document LIO7794, Second Cinven CRA Report, paragraphs 100-105; Document LIO7801, Second HgCapital CRA Report, paragraph 106–109.

(b) Delayed nature of investment returns: the CMA's *ex ante* replacement cost is understated as it is does not take into account the time difference between the investment and the time when the value of those investments is realised.[215]

(c) Option value for sunk costs: If there is uncertainty regarding the value that can be realised from an investment, and that investment cannot be reversed, then the choice of whether or not to invest has an option value. Before investing, a firm can wait to see what happens to the price of the product and hence the value of the investment. The more uncertainty there is, the greater the value in being able to wait before investing. However, the degree of uncertainty around achieving a successful investment, coupled with the fact that the investment to develop Liothyronine Tablets is largely sunk and cannot be recovered, implies that the option value could be substantial. By not factoring in this value, the CMA's *ex ante* replacement cost is likely to be significantly underestimating the true cost for an entrant.[216]

3.212 The CMA does not consider it appropriate, in its *ex ante* replacement cost calculation, to account for the Parties' proposed adjustments relating to risk aversion, delayed nature of investment returns and option values for sunk costs. Adjusting for each element would move away from achieving the underlying objective of valuing Product Rights, that is, to revalue the Product Rights that Advanz already holds so that the CMA's Cost Plus reflects a meaningful, reliable and verifiable capital value for the purposes of an economic cost assessment. The CMA has used actual and potential entrants' costs as a proxy for the replacement cost of Product Rights. The Parties' submissions, however, have misconstrued the purpose of the valuation exercise and attempt to determine an asset valuation that is more suitable for an investment appraisal for a firm considering entry than its actual purpose of determining an efficient cost estimate of Product Rights that are held by the incumbent monopolist.

3.213 In addition to these concerns, the CMA considers that the Parties' proposed adjustments are also unnecessary for the following reasons:

(a) With respect to risk aversion:

(i) Based on CRA's methodology, a firm that spends £2.1 million would make three entry attempts and would have a 70% likelihood of successful entry, based on the inputs into the CMA's sensitivity (i.e. £698k per attempt and

[215] Document LIO7794, Second Cinven CRA Report, paragraphs 106-107; Document LIO7801, Second HgCapital CRA Report, paragraph 110.
[216] Document LIO7794, Second Cinven CRA Report, paragraph 108; Document LIO7801, Second HgCapital CRA Report, paragraph 110.

33% success rate).[217] Given that potential entrants have indicated that each entry attempt is unlikely to be independent or identical, the likelihood of successful entry is likely to be closer to 100%, even with a lower probability of success.[218,219]

(ii) The CMA's approach to the *ex ante replacement cost* estimates an asset value in which most of the risks associated with developing Liothyronine Tablets have been accounted for in the asset value. The CMA does not consider it appropriate to inflate the already overstated replacement cost further to account for any purported risk premium that a risk-averse firm would require. In any event, the CMA already provides for a 5% sensitivity on the rate of return to capture any factors that might result in investors requiring a higher rate of return for an investment in Liothyronine Tablets, by comparison to other investments in pharmaceutical companies.

(b) With respect to adjustments concerning the delayed nature of investment returns, this is not a relevant consideration in assessing costs incurred. Advanz was already in possession of the Product Rights at the start of the Infringement Period and Advanz's investors did not face any delay in achieving investment returns. In fact, Advanz would have recovered its actual entry costs prior to the start of the Infringement Period. The CMA allows for the opportunity costs of holding the notional value of Product Rights in its Cost Plus assessment from the first day of the Infringement Period.

(c) With respect to the argument that the asset value should be further increased to account for the option value of sunk costs, this analysis fails to take into account two factors:

(i) In the Liothyronine Tablets market, prices are not volatile and not subject to exogenous shocks that would likely create investor uncertainty about the recoverability of sunk costs. In that respect, the option value for the sunk costs of investing in Liothyronine Tablets – particularly during the Infringement Period – is likely to be negligible.

[217] If the same analysis were carried out using a constant 50% success rate, the likelihood of successful entry after three attempts would be 88%. If the probability of success was 66%, the likelihood of successful entry after three attempts would be 96%.

[218] See paragraph 3.209 above.

[219] For example, the likelihood of successful entry after three attempts is 82% if the probability of success improves with each successive attempt (i.e. the probability of success with the first attempt is still only 33%; but improves to 42% when the same firm makes a second attempt (25% improvement on previous attempt); and finally the third attempt has a 53% chance with the third attempt (25% improvement on the second attempt)). If the chances improve by 50% with each successive attempt, the likelihood of entry after three attempts is 92%. The CMA does not have data available to model this accurately, but the illustrative example demonstrates the degree to which the CMA's modelling assumptions err in favour of the Parties.

(ii) The value of investments in research and development includes the value of the information, provided by the early stage research and development phase, on the ability of the company to successfully develop the relevant product. In that context, the kind of option value model suggested by the Parties that focuses on the option to delay would not be effective in practice at valuing investments of this nature.

In any event, the option value is not a relevant consideration for determining the efficient replacement cost of Advanz's Product Rights, as the Product Rights were already in its possession at the start of the Infringement Period.

3.214 For these reasons, the CMA does not consider it appropriate to adjust the asset value to account for the Parties' proposed adjustments relating to risk aversion, the delayed nature of investment returns and the option value for sunk costs.

e. Conclusions on the CMA's Product Rights valuation

3.215 The CMA's Cost Plus is based on a Product Rights valuation of [✂], which is the upper estimate of the higher of the two successful entrants' costs and this acts as a proxy for the efficient replacement cost of Advanz's Product Rights. The reasonable rate of return – the Plus – is determined by applying the WACC to the value of the Product Rights. The return allowed for in the CMA's Cost Plus represents the required rate of return for an efficient, hypothetical firm operating in the Liothyronine Tablets market in the UK during the Infringement Period.

3.216 In response to representations, the CMA has carried out a sensitivity assessment on its Product Rights valuation of [✂]. The CMA's sensitised *ex ante* replacement cost estimate is derived from a probabilistic model that estimates the expected cost of entry based on information from failed, potential and successful entrants. The CMA's sensitivity ranges between £1.1 to £2.1 million.[220] On a cautious basis, the CMA uses the upper bound of the sensitivity range for the purposes of its Cost Plus assessment, rounding up to £2.1 million. As explained in paragraph 3.209 above, the model's assumptions err in favour of the Parties and are likely to overstate the replacement cost that an efficient entrant would incur in practice. This is reflected by the significant difference between the CMA's upper end estimate of £2.1 million and the actual costs incurred by Teva and Morningside to enter the market: it is [✂] as Teva's entry costs of [✂] and [✂] than Morningside's entry costs of [✂].

3.217 Despite this, even if the CMA's sensitised *ex ante replacement cost* estimate of £2.1 million is used for the valuation of Product Rights and the CMA's sensitised

[220] If the CMA had used the lower end estimate of Teva and [PE1]'s costs, the CMA's *ex ante replacement cost* would range from [✂] to [✂], with a midpoint of [✂].

rate of return of 15% is applied to this amount, the CMA still finds that Advanz's prices during the Infringement Period were excessive and unfair. The finding of abuse is therefore unaffected by the CMA's sensitivity on Product Rights.

3.218 Having established the £2.1 million upper-end replacement cost estimate, the CMA has applied two sensitivities on the amortisation profile covering (i) no amortisation and (ii) amortisation over 20 years from the start of the Infringement Period. These amortisation sensitivities are applied on a precautionary basis as a cross-check because the UEL and amortisation profile of the Product Rights are areas of judgement.

III. WACC

3.219 As explained further in Annex 4, while in the CMA's view, the methodology used by it in arriving at a reasonable rate of return of 10% is appropriate and reliable, as a cross-check, a sensitivity using a 15% WACC has been applied.

3.220 Applying a 15% WACC allows investors a return consistent with the higher end of the range, which is 5% above the central estimate for Cost Plus purposes (see Annex 4).

3.221 In applying this higher WACC, the CMA has not applied 15% to the working capital element of the capital employed. As explained at paragraphs 3.148 to 3.150 above, the approach to estimating working capital already significantly favours the Parties as it is based on Advanz's actual working capital (and so its pricing conduct) despite the fact that the receivables balances resulting from a product being sold at an inflated price do not represent an efficient level of capital employed in the business: the high price inflates the level of receivables proportionately. Applying a 15% WACC to a significantly inflated working capital balance does not, in the CMA's view, represent a reasonable or realistic estimate of efficient capital costs associated with supplying Liothyronine Tablets. Further, the majority of the working capital balance is receivables. Capital tied up in the receivables balance is likely to be exposed to less risk than the business as a whole. The CMA has therefore applied its upper-end 15% WACC to intangible and tangible fixed assets only.

IV. Conclusions regarding the CMA's sensitivities to Cost Plus

3.222 The combined result of applying the sensitivities set out above to Cost Plus for (i) common cost allocation, (ii) the approach to Product Rights and (iii) a reasonable rate of return (i.e. WACC) is set out in Table A3.10 below. This is referred to as Cost Plus with sensitivities.

Table A3.10: Cost Plus with sensitivities

£s	2009	2010	2011	2012	2013	2014	2015	2016	2017	Simple Average
Cost Plus	2.08	2.10	3.12	2.75	3.99	5.11	5.63	9.87	9.78	4.94
Activity-based costing	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Product Rights sensitivity[221]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
15% WACC	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Cost Plus with sensitivities	4.94	4.88	6.00	5.02	6.34	7.49	7.51	12.08	11.88	7.35

Source: CMA Cost Plus assessment – 'Cumulative sensitivities' tab.

G. Summary of Cost Plus assessment

3.223 As set out above, the purpose of the CMA's Cost Plus calculation is to assess whether Advanz's prices were materially above the '*costs actually incurred*' by supplying Liothyronine Tablets plus a reasonable rate of return and thus excessive and unfair within the meaning of the Excessive Limb of *United Brands*.

3.224 The subsequent application of sensitivities to the CMA's Cost Plus calculation serves as a cross-check to test the overall results obtained. The sensitivities test further some of the key inputs and assumptions by factoring in:

(a) An adjusted version of Advanz's activity-based costing analysis to allocate common costs;

(b) An upper end estimate of the C valuation and different amortisation profiles of the Product Rights; and

(c) A higher rate of return, i.e. a WACC of 15% (except in relation to working capital).

3.225 The combined results of the CMA's analysis are detailed in Table A3.11 and plotted against the relevant ASPs in Figure A3.3 below.

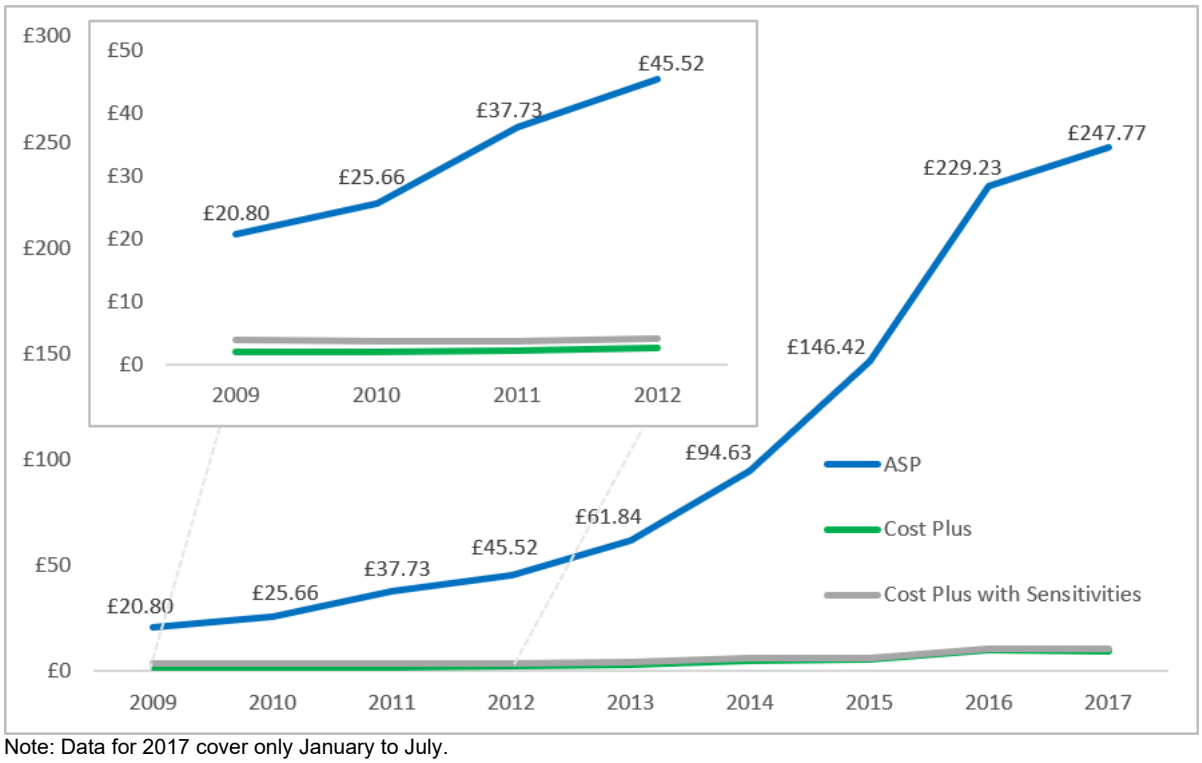
[221] This uses the higher of the outturn costs from the two potential Product Right sensitivities of £2.1 million with no amortisation and £2.1 million amortised over 20 years from 2009.

Table A3.11: ASP compared with Cost Plus and Cost Plus with Sensitivities in the Infringement Period

	2009	2010	2011	2012	2013	2014	2015	2016	2017*	Simple average
ASP	20.80	25.66	37.73	45.52	61.84	94.63	146.42	229.23	247.77	
Advanz's Cost Plus	2.08	2.10	3.12	2.75	3.99	5.11	5.63	9.87	9.78	4.94
Advanz's Cost Plus with sensitivities	4.94	4.88	6.00	5.02	6.34	7.49	7.51	12.08	11.88	7.35
Note: Data for 2017 cover only January to July.										

Source: CMA Cost Plus assessment – 'Differentials' tab.

Figure A3.3: Advanz's ASPs over time compared with Cost Plus and Cost Plus with Sensitivities estimates (£s)



Note: Data for 2017 cover only January to July.
Source: CMA analysis.