EUROPEAN COMMISSION
Competition DG

CASE AT.40394 – Aspen

(Only the English text is authentic)

ANTITRUST PROCEDURE

Council Regulation (EC) 1/2003

Article 9 Regulation (EC) 1/2003

Date: 10/02/2021

Brussels, 10.2.2021
C(2021) 724 final

COMMISSION DECISION

of 10.2.2021

relating to a proceeding under Article 102 of the Treaty on the Functioning of the European Union (TFEU) and Article 54 of the EEA Agreement

Case AT.40394 – ASPEN

(Text with EEA relevance)

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TABLE OF CONTENTS

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(Text with EEA relevance)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union[1],

Having regard to the Agreement on the European Economic Area[2],

Having regard to Council Regulation (EC) No 1/2003[3] of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty, in particular Article 9(1) thereof,

Having regard to the Commission Decision of 15 May 2017 to initiate proceedings in this case,

Having expressed concerns in the Preliminary Assessment of 19 June 2020,

Having given interested third parties the opportunity to submit their observations pursuant to Article 27(4) of Regulation (EC) No 1/2003 on the commitments offered to meet those concerns,

After consulting the Advisory Committee on Restrictive Practices and Dominant Positions,

Having regard to the final report of the Hearing Officer,

Whereas:

[1] OJ C 115, 9.5.2008, p. 47.

[2] OJ L 1, 3.1.1994, p. 3 'EEA Agreement'.

[3] OJ L 1, 4.1.2003, p. 1, 'Regulation 1/2003'. With effect from 1 December 2009, Articles 81 and 82 of the EC Treaty have become Articles 101 and 102 TFEU, respectively. The two sets of provisions are, in substance, identical. For the purposes of this Decision, references to Articles 101 and 102 TFEU should be understood as references to Articles 81 and 82, respectively, of the EC Treaty where appropriate. The TFEU also introduced certain changes in terminology, such as the replacement of 'Community' by 'Union' and 'common market' by 'internal market'. Where the meaning remains unchanged, the terminology of the TFEU will be used throughout this Decision.

1. INTRODUCTION

(1) This Decision is addressed to Aspen Pharmacare Holdings Ltd and ASPEN PHARMA IRELAND LIMITED (collectively referred to as 'Aspen'). It relates to concerns of excessive pricing by Aspen with respect to six cancer medicines in the European Economic Area, excepting Italy[4] ('EEA'[5]). Those medicines are Alkeran IV, Alkeran Oral, Lanvis, Leukeran, Myleran and Purinethol (the 'Products').

(2) In its preliminary assessment adopted on 19 June 2020 (the 'Preliminary Assessment'), the Commission found that Aspen may have imposed unfair prices within the meaning of Article 102(a) TFEU and Article 54(a) of the EEA Agreement[6] in the form of excessive prices. Aspen's conduct started in some Member States mid-2012 with very high price increases, often by several hundred percent and resulted in very high price and profitability levels of those medicines. The Preliminary Assessment was based on an analysis of Aspen's practices during its 2013-2019 financial years, that is the period from 1 July 2012 until 30 June 2019 (the 'Relevant Period'); and the Commission has no indication that Aspen's pricing practices would no longer be ongoing.

(3) While Aspen disagrees with the provisional conclusion of the Commission in its Preliminary Assessment, it nevertheless has offered commitments pursuant to Article 9(1) of Regulation 1/2003 to meet the concerns expressed by the Commission. As further explained below, this Decision finds that Aspen's commitments remove the Commission's concerns identified in its Preliminary Assessment and makes those commitments binding on Aspen.

2. THE UNDERTAKING CONCERNED

(4) Aspen is an international pharmaceutical company, headquartered in South Africa. It supplies mainly generic medicines used as anaesthetics or in the treatment of thrombosis, the endocrine system or cancer. In its financial year ('FY') 2020 ending 30 June 2020, Aspen generated total revenues of ZAR 38.6 billion (approx. EUR 2.1 billion) worldwide, out of which ZAR 14.2 billion (approx. EUR 0.8 billion) was generated in the EEA.

(5) Aspen's group holding entity is Aspen Pharmacare Holdings Ltd in South Africa. In the EEA, the Aspen group operates a number of subsidiaries that manage the Products in the EEA, including the fully owned ASPEN PHARMA IRELAND LIMITED, based in Ireland.

3. PROCEDURAL STEPS UNDER REGULATION (EC) NO 1/2003

(6) On 15 May 2017, the Commission opened proceedings with a view to adopting a Decision under Chapter III of Regulation 1/2003. On 19 June 2020, the Commission adopted a Preliminary Assessment as referred to in Article 9(1) of Regulation 1/2003 which set out the Commission's competition concerns of excessive pricing by Aspen in relation to the Products in the EEA. This Preliminary Assessment was notified to Aspen on 22 June 2020.

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[4] The exclusion of Italy is because on 29 September 2016, the Italian Competition Authority (Autorità Garante della Concorrenza e del Mercato) adopted an Article 102 TFEU infringement Decision in Case A-480 *Incremento Prezzo Farmaci Aspen* with respect to Aspen's unfair pricing practices regarding Alkeran, Leukeran, Purinethol and Lanvis. The Council of State *(Consiglio di Stato)* upheld that Decision in its Judgment of 20 February 2020 in Case No 8447/2017.

[5] "EEA" refers to the European Economic Area that comprises the Union Member States together with Iceland, Liechtenstein and Norway (hereinafter 'Member States'; for the purposes of this Decision, this reference excludes Italy but includes the United Kingdom as regards references to points in time until 31 December 2020).
Although the United Kingdom withdrew from the European Union as of 1 February 2020, according to Article 92 of the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community (OJ L 29, 31.1.2020, p. 7, 'Withdrawal Agreement'), the Commission continues to be competent to apply Union law as regards the United Kingdom for administrative procedures which were initiated before the end of the transition period (ending on 31 December 2020). EEA and Union law is no longer applicable in the United Kingdom after the transition period.

[6] Article 54 of the EEA Agreement contains a provision on competition analogous to Article 102 TFEU. In this Decision, the Commission's assessment of Article 102 TFEU equally applies to Article 54 of the EEA Agreement without further explicit references to Article 54 of the EEA Agreement.

(7) On 9 July 2020, Aspen submitted commitments (the 'Proposed Commitments') to the Commission in order to meet the concerns expressed in the Preliminary Assessment.

(8) On 15 July 2020, the Commission published a notice in the Official Journal of the European Union pursuant to Article 27(4) of Regulation 1/2003 ('the Article 27(4) notice'), summarising the case and the Proposed Commitments and inviting interested third parties to give their observations on the Proposed Commitments within 2 months following publication.

(9) The Commission received 30 observations on the Proposed Commitments by various respondents, including national pricing and reimbursement authorities, consumer organisations, cancer organisations and patient organisations at Union and national level.

(10) On 9 December 2020, the Commission informed Aspen of the observations received from interested third parties following the publication of the notice. On 28 January 2021, Aspen submitted revised, final commitments (the 'Final Commitments', which are attached in Annex 3).

(11) On 5 February 2021, the Advisory Committee on Restrictive Practices and Dominant Positions was consulted.

4. PRELIMINARY ASSESSMENT

4.1. Background to the practices concerned

(12) The Products are mostly essential medicines for human use in the treatment of cancer, such as haematological tumours, with the active pharmaceutical ingredients ('APIs') melphalan, mercaptopurine, chlorambucil, tioguanine and busulfan. They are prescription medicines sold under the brand names Alkeran IV and Alkeran Oral (melphalan), Purinethol (mercaptopurine), Leukeran (chlorambucil), Lanvis (tioguanine) and Myleran (busulfan).

(13) The patent protection for the Products expired approximately 50 years ago. The Products do not benefit from any other type of legal exclusivity.

(14) Aspen acquired the Products from GlaxoSmithKline plc ('GSK') in 2009 as part of a bundle of transactions paid for with Aspen shares. During the transitional period, GSK continued to manage the Products on behalf of Aspen until commercial contracts and marketing authorisations were transferred to Aspen in 2011. Aspen has since been outsourcing the manufacturing and packaging of the Products as well as most of the commercialisation and distribution to third parties.

(15) In 2011, when Aspen took over the management of the Products, it developed a plan to increase the prices for the Products with "*a big push*".[7] As described further in Section 4.6.2, Aspen sequenced a series of very high price increases in a way that defeated the external price referencing systems in various Member States. In certain Member States, Aspen imposed price increases by threatening to de-list or to withdraw the Products. After having imposed the increased prices, often by several hundred percent, Aspen maintained the high prices, in some Member States from 2012.

4.2. The regulatory framework

4.2.1 Marketing authorisation

(16) In the EEA, medicines (whether originator or generic versions) may only be placed on the market after they have obtained a marketing authorisation. A marketing authorisation can be obtained either through a centralised procedure before the European Medicines Agency or through national

[7] Email dated 26 May 2011 from [Aspen employee]* to [Aspen employee] regarding "Onco Pricing opportunity priority - Europe".

** Parts of this text have been edited to ensure that confidential information is not disclosed. Those parts are replaced by a non-confidential summary in square brackets or are shown as […].*

authorisation procedures.[8] Irrespective of the procedure, obtaining a marketing authorisation even for generic medicines is a resource-intensive and long process that, in principle, can take between 12 and 18 months for generic medicines and even longer for originator medicines.[9]

(17) The Products were initially placed on the different markets in Europe by GSK in the 1950s, based on national marketing authorisation procedures. The marketing authorisations were transferred to Aspen in 2011.

4.2.2 Pricing and reimbursement policies

(18) In the EEA, pricing and reimbursement rules and policies for originator or generic medicines are an exclusive competence of Member States. This leads to a large variety in pricing regulation across Member States due to historical, political, legal and economic developments, as well as in the overall organisation and funding of the national healthcare system in each Member State.

(19) Member States may therefore apply different pricing schemes that are typically based on negotiations between healthcare bodies of Member States and manufacturers. Moreover, additional cost-containment measures may apply in the different Member States to reduce the prices for medicines, including discounts with a direct influence on the price effectively charged.[10]

(20) Pricing schemes may also be coupled with references to the price of the same medicine in other Member States. Most Member States incorporate such an "external reference pricing system" in the national price formation process to limit in their territory the ability of pharmaceutical companies to impose high prices for their medicines. External reference pricing systems typically use a set of benchmarks (namely list prices) of one or several Member States (the so-called "price-reference basket") to determine maximum price levels for certain medicines in their territory. This means that price fluctuations in one Member State may directly, or indirectly, influence price levels in other Member States.

(21) Health systems rely also on reimbursement policies to contain spending and to exert a more indirect influence on prices. For instance, without reimbursement status, doctors may prefer not to prescribe a medicine or patients may not be able to pay for it. Conversely, the reimbursement status may also be essential to ensure proper healthcare and access to medicines patients really need. Most medicines used in the treatment of cancer, including Aspen's Products, are generally fully reimbursed in most EEA Member States. This ensures that patients have access to essential cancer medicines.

(22) Since pharmaceutical companies can unilaterally withdraw their products from reimbursement lists, maintaining reimbursement status or not for the Products was a powerful bargaining chip for Aspen in the price negotiation process with pricing and reimbursement authorities of the Member States. As shown below, in the Preliminary Assessment, the Commission expressed concerns that Aspen exploited this bargaining chip in certain cases by threatening to unilaterally remove the medicines from reimbursement lists (see Section 4.6.2.2).

(23) Further to the reimbursement status of the Products, also external reference pricing is, as explained in Recital (20), of particular relevance for Aspen's price negotiation process, as the Preliminary

[8] The national marketing authorisation procedures include the Decentralised Procedure, the Mutual Recognition Procedure or the national procedure.

[9] 'Originator' medicine is defined as a novel drug that was under patent protection when launched onto the market. 'Generic' medicine is defined as a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as a reference (originator) medicinal product and whose bioequivalence with the reference medicinal product has been demonstrated. When applying for a marketing authorisation, originators are required to support their application with results of lengthy (pre-) clinical tests and clinical trials to show that a new medicine is safe, effective and of good quality. Generics may be exempted from this requirement if it is shown that the generic medicine is bioequivalent to a medicine previously authorised.

[10] Other measures may include so-called statutory price reductions, rebates or claw backs. See the Commission's Pharmaceutical Sector Inquiry (2009), section 2.3.2 (supply-side practices): https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff working_paper_part1.pdf

Assessment found that Aspen sequenced price increases in various Member States in a particular order to defeat the purpose of the external reference pricing systems (see Section 4.6.2.3).

4.3. Relevant product markets

General introduction

(24) According to paragraph 7 of the Market Definition Notice,[11] "a relevant product market comprises all those products and/or services which are regarded as interchangeable or substitutable by the consumer, by reason of the products' characteristics, their prices and their intended use". Paragraph 36 explains that an "analysis of the product characteristics and its intended use allows the Commission, as a first step, to limit the field of investigation of possible substitutes. However, product characteristics and intended use are insufficient to show whether two products are demand substitutes. Functional interchangeability or similarity of characteristics may not, in themselves, provide sufficient criteria, because the responsiveness of customers to relative price changes may be determined by other considerations as well".

(25) According to settled case-law, it is not sufficient in this respect to assess the interchangeability or the substitutability of goods in relation to their objective characteristics, but the competitive conditions and the structure of supply and demand must also be taken into consideration.[12]

Delineating relevant product markets for pharmaceuticals

(26) In the context of medicines, therapeutic substitutability is a necessary precondition for another medicine to be potentially capable of exercising significant competitive constraints on a given medicine. Medical guidelines can provide a first indication for therapeutic substitutability. They are generally written by leading experts in the field that summarise the standard of care. When such guidelines recommend that two or more medicines can be used in the same way for a particular medical indication, this may be an indication for therapeutic substitutability. In addition, also actual prescription practices may have to be taken into account. Actual prescription practices may be different from medical guidelines for a number of reasons.

(27) However, two medicines may be therapeutically (functionally) substitutable to a certain degree but they may not exercise significant competitive constraints upon each other. For instance, when prices of a medicine are, or increase, significantly above competitive levels, customers may, as a matter of fact, not switch to other medicine(s) defeating those price levels or increases. Therapeutic substitutability is therefore a necessary but not a sufficient condition for two medicines to be in the same product market. To be in the same product market, medicines have to constrain each other also significantly economically.

(28) When defining in the present case the relevant product market, it is therefore necessary to also identify whether other medicines sufficiently constrain Aspen's commercial conduct concerning the Products, including with respect to pricing. The relevant question to be answered therefore is whether significant switching to therapeutic alternatives has occurred or would occur so as to constrain Aspen significantly economically.

(29) Where medicines have lost their patent protection, the Commission and a number of other competition authorities in the Union have observed that medicines based on other molecules often do not constrain the off-patent medicine in a significant way and that therefore the relevant product

[11] Commission Notice on the definition of relevant market for the purposes of Community competition law (OJ C 372, 9.12.1997, p. 5).

[12] Judgment of the Court of Justice of 23 January 2018, *F. Hoffmann-La Roche and Others*, C-179/16, EU:C:2018:25, paragraph 51; Judgment of the Court of Justice of 9 November 1983, *Nederlandsche Banden-Industrie-Michelin v Commission*, 322/81, EU:C:1983:313, paragraph 37.

market was regularly defined at molecule level.[13] For example, in *Pfizer/Hospira*,[14] the Commission found that cytarabine, an off-patent chemotherapy agent used for different types of cancer treatment affecting blood cells (concerning cancers not treated by the Products investigated in this Decision), could not be substituted by other molecules. The Union Courts, the Commission and national competition authorities have observed that generic medicines based on the same molecule are typically the closest substitutes to off-patent originator medicines and that they are in fact specifically designed to compete with those originator medicines.[15] In the Commission's previous cases, the analysis of constraints regarding off-patent medicines led also to product market definitions even narrower than at molecule level.[16] Furthermore, the Commission also found that the use of a certain medicine can be limited to a particular stage of the disease[17] or to a certain line of treatment (for example, initial treatment *versus* relapse treatment).[18]

(30) In cases concerning cancer medicines, the Commission found that differences in efficacy, risk/side effects and the price of the medicine are factors that limit therapeutic and/or economic substitutability.[19]

Defining the relevant product markets for the Products

(31) To identify the relevant product market, in its Preliminary Assessment, the Commission first assessed the pharmacological characteristics of the respective medicines and identified their most relevant medical uses.

(32) Subsequently, it examined whether Aspen's products have therapeutic substitutes for the specific medical uses and, if so, assessed the extent of therapeutic differentiation between different medicines used for a given medical use (both between different molecules (INNs)[20], or between different formulations of the same INN).

(33) The Commission based its preliminary analysis specifically on: the European Society for Medical Oncology Guidelines ('ESMO') as they evolved over time as of 2009; the opinions of clinical experts in the respective medical fields; the National Haematology Associations' replies during the Commission investigation; the replies during the Commission investigation from the candidate therapeutic substitutes; and Aspen's own assessment evidenced by the documents collected during inspections.

(34) Where necessary, and in particular where the Commission preliminarily found that there may be therapeutic substitutes (other than generics of the same formulation) for the respective Aspen

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13 Commission Decision of 9 November 2012 in Case No COMP/M.6258 – *Teva/Cephalon*, Recitals 12, 37f., 64f., 94; Commission Decision of 3 August 2010 in Case No M.5865 – *Teva/Ratiopharm*, Recital 26; Commission Decision of 4 February 2009 in Case No COMP/M.5253 – *Sanofi-Aventis/Zentiva*, Recital 25f.

14 Commission Decision of 4 August 2015 in Case No COMP/M.7559 - *Pfizer/Hospira*.

15 See Judgment of the Court of Justice of 30 January 2020, *Generics (UK) Ltd. and Others v Competition and Markets Authority*, C-307/18, EU:C:2020:52, paragraphs 130-131 (emphasising the dynamic nature of interchangeability or substitutability and hence market definition and that after patent expiry a new delineation of the market can be warranted); Judgment of the Court of Justice of 6 December 2012, *AstraZeneca AB and AstraZeneca plc v European Commission*, C-457/10 P, EU:C:2012:770, paragraph 59; Office of Fair Trading, Decision of 12 April 2011, *Reckitt Benckiser Healthcare (UK) Limited and Reckitt Benckiser Group plc*, No. CA98/02/2011, Case CE/8931/08; Italian Competition Authority (Autorità Garante del Mercato e della Concorrenza), Decision of 11 January 2012 in case A431 *Ratiopharm/Pfizer;* French Competition Authority (Autorità de la Concurrence), Decision of 14 May 2013 on practices implemented in the pharmaceutical sector, 13-D-11; French Competition Authority (Autorità de la Concurrence), Decision of 20 December 2017 regarding practices implemented in the sector of transdermal patches of fentanyl, 17-D-25; see also *Federal Trade Commission v. AbbVie Inc. et al.* (3d Cir.), 19 July 2019, Case 18-2621.

16 See, for example, Commission Decision of 4 August 2015 in Case No COMP/M.7559 - *Pfizer/Hospira*, where the Commission, in accordance with previous decisions, observed that galenic aspects, that is, dosage, route of administration, and pharmaceutical form, may limit a medicine's substitutability.

17 See cases COMP/M.5476 – *Pfizer/Wyeth*, Decision of 17 July 2009; COMP/M.3354 – *Sanofi-Synthelabo/Aventis*, Decision of 26 April 2004.

18 See cases COMP/M.5865 – *Teva/Ratiopharm*, Decision of 3 August 2010; COMP/M.5476 – *Pfizer/Wyeth*, Decision of 17 July 2009.

19 See cases COMP/M.8523 – *BD/Bard*, Decision of 18 October 2017; COMP/M.7559 – *Pfizer/Hospira*, Decision of 4 August 2015; COMP/M.5999 – *Sanofi Aventis/Genzyme*, Decision of 12 January 2011; COMP/M.5865 – *Teva/Ratiopharm*, Decision of 3 August 2010.

20 International Non-proprietary Names (INN) facilitate the identification of pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognized and is public property. A non-proprietary name is also known as a generic name.

product, the Commission further analysed the significance of economic constraints for defining the relevant market.

4.3.1 Melphalan

(35) Melphalan[21] is an active substance that is used in the treatment of certain types of cancer and belongs to a group of medicines called cytotoxics (also called chemotherapy).

(36) Melphalan is commercialised in two forms corresponding to different routes of administration, namely tablets ('melphalan oral')[22] and intravenous form consisting of powder and solvent, ('melphalan IV')[23]. Aspen commercialises melphalan oral under the commercial names 'Alkeran tablets' or 'Alkeran 2mg tablets' and melphalan IV under 'Alkeran IV', respectively.

(37) Melphalan oral and melphalan IV both appear to be predominantly used for the (first line) treatment of multiple myeloma, a type of haematological cancer. Both of them are only marginally used for certain other indications. The analysis could therefore be limited to medicines treating multiple myeloma.

(38) Multiple myeloma patients are typically divided in two groups: patients that are eligible to receive autologous stem cell transplantation ('ASCT') and patients that are not eligible for ASCT. ASCT-eligible patients either below 65-75 years of age or older but fit and, therefore, in a good clinical condition to tolerate the side effects of the ASCT procedure.

4.3.1.1. Melphalan IV

(39) The Commission's investigation revealed that in the treatment of ASCT-eligible multiple myeloma patients, melphalan IV cannot be replaced by any other API, or another formulation of melphalan. Melphalan IV is essential in the preparative regimen preceding the stem cell transplantation. This regimen requires the administration of a very high dose of melphalan intravenously to the patient that cannot be administered orally, because it would not be tolerated by the patient.

(40) Therefore, the Commission reached the preliminary conclusion that the relevant product market for melphalan IV comprises all medicines containing melphalan API in intravenous formulation (allowing for an administration of a high dose of the API at once).

4.3.1.2. Melphalan oral

(41) The Commission's investigation revealed that, in the treatment of non-ASCT eligible multiple myeloma patients (that is patients that do not require the administration of a high dose of melphalan intravenously), melphalan-based regimens[24] may not have therapeutic substitutes considering differences in product characteristics, prescription practices and the regulatory status (such as, in some cases, reimbursement status) of the various regimens. The Commission's investigation revealed that while the use of other regimens[25] – predominantly lenalidomide-based regimens – might in principle represent potential alternatives, certain potentially important patient groups (for example elderly populations, populations with renal failure and other comorbidities) may not have alternatives to melphalan-based treatments. Moreover, in view of the significant differences in the

[21] See European Pharmaceutical Marketing Research Association (EphMRA), 'EPHMRA Anatomical Classification Guidelines' (2019) (the 'EphMRA Guidelines 2019'), https://www.ephmra.org/media/2485/atcguidelines2019final.pdf, p. 96, ATC code: L01AA03.

[22] Melphalan oral is commercialised as tablets, each containing 2mg of the active substance melphalan.

[23] Melphalan IV is commercialised as a combination of powder and solvent. It is sold in units comprising two vials: a vial that contains melphalan hydrochloride equivalent to 50 mg melphalan and povidone, a water-soluble polymer in the form of powder, and a vial that contains the solvent. After mixing the powder with the solvent, the solution is administered to patients as an injection or infusion.

[24] The two melphalan-based regimens are: bortezomib / melphalan oral / prendisone; and melphalan oral / prendisone / thalidomide. Regimen in the case at hand refers to a treatment plan that consists of a combination of various medicines, including melphalan oral, administered in specific doses and frequencies in each treatment cycle.

[25] These are predominantly lenalidomide-based regimens, namely lenalidomide / low-dose dexamethasone (so-called 'Rd') and lenalidomide / low-dose dexamethasone / bortezomib ('VRd') and cyclophosphamide-based regimens, namely bortezomib / cyclophosphamide / dexamethasone ('VCD') and cyclophosphamide / thalidomide / dexamethasone ('CTD').

price levels of the main potential choices of treatment for non-ASCT eligible multiple myeloma patients, that is to say melphalan-based regimens and the lenalidomide-based regimens, with the latter being more costly, the Commission considered that melphalan-based regimens may constitute a separate product market.

(42) Accordingly, the Commission reached the preliminary conclusion that the relevant product market for melphalan oral may comprise all medicines containing melphalan as an API with an oral route of administration (tablet).

4.3.2 Mercaptopurine

(43) Mercaptopurine[26] is an anticancer medicine that belongs to the group 'antimetabolites' and is commercialised by Aspen under the commercial name 'Purinethol'.

(44) Mercaptopurine is prescribed overwhelmingly for Acute Lymphocytic Leukaemia (ALL), which is a cancer of the white blood cells called lymphocytes. The Commission's analysis in the Preliminary Assessment of the relevant product market for mercaptopurine was therefore limited to ALL. There are two oral formulations, a tablet and an oral suspension. As both can be used for the same indication, both may be considered as part of the relevant market from the perspective of the product under investigation, mercaptopurine tablets. For the purposes of the Preliminary Assessment, it has been left open whether the price difference between the tablet and the oral suspension may suggest separate markets for both.

(45) The standard chemotherapy treatment for ALL consists of three main steps, called phases: during different phases, different medicines are used. The main use of mercaptopurine in the treatment of ALL is during the maintenance phase to prevent the disease returning (relapse).[27]

(46) The Preliminary Assessment found that mercaptopurine, due to its pharmacological properties, is an essential medicine, with no therapeutic alternatives for ALL patients.

(47) Therefore, the Commission reached the preliminary conclusion that the relevant product market for mercaptopurine comprises only medicines containing mercaptopurine as the active pharmaceutical ingredient.

4.3.3 Chlorambucil

(48) Chlorambucil[28] is an anti-cancer medicine that belongs to a class of medicines called antineoplastics and is commercialised by Aspen under the commercial name 'Leukeran'.

(49) Chlorambucil is prescribed for Chronic Lymphocytic Leukaemia (CLL). For other diseases, chlorambucil appears to be rarely used. Therefore, the Commission's analysis in the Preliminary Assessment of the relevant product market for chlorambucil was limited to CLL.

(50) The Commission's investigation revealed that chlorambucil (as monotherapy or in combination) may not have substitutes. For instance, bendamustine and ibrutinib may be considered only limited functional substitutes in certain countries (for example, bendamustine is used for a different patient population than chlorambucil, they have different safety/tolerability profiles, and have different modes of administration) and the medical practice differs in each country. Even if chlorambucil, bendamustine and ibrutinib might be considered therapeutically substitutes, the Commission considered, in the Preliminary Assessment, that bendamustine and ibrutinib have not exercised any significant competitive constraint on chlorambucil in particular due to the difference in prices (resulting from market exclusivity for bendamustine or patent protection for ibrutinib).

[26] See EphMRA Guidelines 2019, ATC code: L01BB02.

[27] See Dossier prepared for Aspen by an external expert who analysed the medical and economic value of the Products ('Global Value Dossier'), here for Purinethol, p. 30.

[28] See EphMRA Guidelines 2019, ATC code: L01AA02.

(51) Accordingly, the Commission reached the preliminary conclusion that the relevant product market for chlorambucil may comprise all medicines containing chlorambucil as API.

4.3.4 Busulfan oral

(52) Busulfan[29] belongs to a group of medicines called cytotoxics and is commercialised by Aspen under the commercial name 'Myleran'.

(53) Busulfan oral mostly plays a role in the treatment of Polycythaemia Vera (PV) and Essential Thrombocythaemia (ET) as second, third or fourth line of treatment, that is when other medicines have failed or are contraindicated. As a result, busulfan oral has a small patient population of older people (older than 70, 75 years) for which other treatments do not work or are contraindicated. Besides the oral formulation of tablets of 2mg, busulfan can be found also as a solution for intravenous application ('IV') – 6 mg/ml concentrate. Aspen does not produce busulfan IV The Commission's investigation has shown that busulfan IV and oral are used for different indications and do not appear to be on the same market due to different medical uses.[30]

(54) Therefore, the Commission reached the preliminary conclusion that the relevant product market for busulfan oral may comprise all medicines containing busulfan as the active pharmaceutical ingredient, which is administered orally.

4.3.5 Tioguanine

(55) Tioguanine[31] belongs to the group of medicines called cytotoxics and is commercialised by Aspen under the commercial name 'Lanvis'.

(56) Tioguanine is authorised for the treatment of Acute Myelogenous Leukaemia (AML) and ALL.

(57) In view of the arrival of newer agents, it currently only plays a limited role in the treatment of these cancers. With regard to ALL, the ESMO guidelines do not mention tioguanine as recommended treatment for ALL at all. With regard to AML, international expert opinion confirms a beneficial role of tioguanine-containing regimens as a treatment of last resort in older AML patients (age>60) and in paediatric AML.[32]

(58) The Commission reached the preliminary conclusion that the relevant product market for tioguanine may comprise all medicines containing tioguanine as API, which are administered for the patient population of older AML patients and paediatric AML patients.

4.4. Relevant geographic markets

(59) The relevant geographic market comprises the area in which the undertakings concerned are involved in the supply and demand of the relevant products and where the conditions of competition are similar or sufficiently homogeneous and can be distinguished from neighbouring areas, in which the prevailing conditions of competition are appreciably different.[33]

(60) The conditions of supply and demand of pharmaceutical products are likely to vary across Member States namely due to different reimbursement rules and different prescribing practices of doctors.

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29 See EphMRA Guidelines 2019, ATC code: L01AB01.

30 Busulfan IV is authorised only for use as part of a 'conditioning' (preparative) treatment before transplantation of haematopoietic progenitor cells. Aspen confirmed that busulfan IV has essentially replaced busulfan oral in this indication. Since busulfan oral is not used anymore for conditioning' (preparative) treatment before transplantation of haematopoietic progenitor cells, the Commission primarily concluded that busulfan oral and busulfan IV are not in the same relevant market due to different medical uses.

31 See EphMRA Guidelines 2019, ATC code: L01BB03.

32 Global Value Dossier for Lanvis, p. 49.

33 See the Commission Notice on the definition of relevant market for the purposes of Community competition law, Official Journal C 372, 9.12.1997, p. 5. See also Judgment of the Court of Justice of 14 February 1978 in *United Brands v Commission*, C-27/76, EU:C:1978:22, paragraph 44; Judgment of the Court of Justice of 9 November 1983, *Michelin v Commission*, C-322/81, EU:C:1983:313, paragraph 26.

Accordingly, the conditions of competition in each Member State are likely to be different from others.

(61) Based on those considerations, the Commission has typically defined the geographic market as national in previous decisions regarding pharmaceutical products.[34] Those above considerations also apply in the present case for the product markets identified in Sections 4.3.1 to 4.3.5, and the Commission thus found, in its Preliminary Assessment, that the relevant geographic markets for the Products are national. In this Decision, the combinations of product markets and those geographic markets where Aspen had sales during the Relevant Period[35] are referred to as 'Relevant Market' or, together, 'Relevant Markets'.

4.5. Aspen's dominance on the Relevant Markets

4.5.1 Principles

(62) According to well-established case-law, dominance is "a position of economic strength enjoyed by an undertaking, which enables it to prevent effective competition being maintained on the relevant market by affording it the power to behave to an appreciable extent independently of its competitors, its customers and ultimately of consumers" .[36]

(63) For dominance to exist, the undertaking concerned must have substantial market power that allows it to have an appreciable influence on the conditions under which competition will develop.[37] However, dominance does not imply that an undertaking has eliminated all opportunity for competition or the absence of any competitive constraint.[38]

(64) The existence of a dominant position derives in general from a combination of several factors.[39] One important factor is the existence of large market shares. In *AstraZeneca,* the Court of Justice held that *"although the importance of the market shares may vary from one market to another, the possession, over a long period, of a very large market share constitutes in itself, save in exceptional circumstances, proof of the existence of a dominant position [...] and that market shares of more than 50% constitute very large market shares...*" .[40] A share of between 70% and 80% is, in itself, a clear indication of the existence of a dominant position in a relevant market.[41] Further, a decline in market shares, which still remain very large, cannot in itself constitute proof of the absence of a dominant position.[42]

(65) Other important factors which the Commission considered when assessing dominance in its Preliminary Assessment are the likelihood of future entry by potential competitors or future expansion by actual competitors, in particular in view of barriers to entry, and the bargaining strength of the undertaking's customers (countervailing buyer power).

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34 See, for instance, Commission Decision 2006/857/EC in Case COMP/A 37.507/F3 – *AstraZeneca*, OJ L 332, 30.11.2006, p. 24-25, Recital 503.

35 See Recital (2).

36 Case C-27/76 *United Brands v Commission,* paragraph 65; See also Judgment of the Court of 13 February 1979, *Hoffmann-La Roche & Co. AG v Commission,* C-85/76, EU:C:1979:36, paragraph 38; and Judgment of the Court of First Instance of 17 September 2007, *Microsoft v Commission,* T-201/04, EU:T:2007:289, paragraph 229.

37 Case C-85/76 *Hoffmann-La Roche v Commission,* paragraph 39.

38 See Case C-27/76 *United Brands v Commission,* paragraph 113.

39 See Case C-27/76 *United Brands v Commission,* paragraph 66.

40 See Judgment of the Court of Justice of 6 December 2012, *AstraZeneca AB and AstraZeneca plc v European Commission,* C-457/10 P, EU:C:2012:770, paragraph 176. See also Case 85/76 *Hoffmann-La Roche v Commission,* paragraph 41.

41 Judgment of the Court of 12 December 1991, *Hilti v Commission,* T-30/89, EU:T:1991:70, paragraph 92; Judgment of the Court of First Instance of 30 September 2003, *Atlantic Container Line and Others v Commission,* Joined Cases T-191/98, T-212/98 to T-2014/98, EU:T:2003:245, paragraph 907; Judgment of the General Court of 25 June 2010, *Imperial Chemical Industries v Commission,* T-66/01, EU:T:2010:255, paragraph 257; and Judgment of the General Court of 29 March 2012, Telefónica, SA and Telefónica de España, SA v European Commission, Case T-336/07, EU:T:2012:172, paragraph 150.

42 Judgment of the Court of First Instance of 30 January 2007, *France Telecom SA v Commission,* T340/03, EU:T:2007:22, paragraph 104.

4.5.2 Assessment

(66) In the vast majority of the Relevant Markets, Aspen has maintained very high market shares during the Relevant Period, very often [90-100]% or between [70-80]% to [90-100]%.[43] The Commission concluded in its Preliminary Assessment that those shares already constitute a clear indication of Aspen's ability to act to an appreciable extent independently of its competitors and customers, and thus of Aspen's dominant position.[44]

(67) As regards barriers to entry, the Commission found in the Preliminary Assessment that the Relevant Markets seem to be characterised by a number of barriers to entry and expansion. These include, amongst others, demanding regulatory requirements for entering a market, namely for obtaining a marketing authorisation (see Section 4.2.1). The Commission also found in the Preliminary Assessment that arranging supply may also be difficult and time-consuming. Those barriers, in view of the limited market size and potentially shrinking volumes in certain markets, seem to have rendered entry or expansion by certain potential entrants less attractive.

(68) Accordingly, the Commission found in its Preliminary Assessment that there was no entry or, where entry happened, it was limited and did not lead to a decrease in prices. Aspen's highly profitable price levels should have been an incentive for timely and competitive entry of other suppliers. Nonetheless, in most of the Relevant Markets, no entry has occurred in the Relevant Period. Even in those markets where some entry eventually occurred, this has happened in most Relevant Markets only after several years of very high prices that were profitably maintained by Aspen and has not led to any significant market share gains for Aspen's competitors. In any case, such entry has not been sufficient to discipline Aspen's conduct and prevent the exercise of substantial market power, such as the imposition and maintenance by Aspen of very high prices.

(69) The Commission's investigation has revealed that future entry and expansion plans appear unlikely to constrain Aspen sufficiently given that the threat of potential entry has not to date had any material impact on Aspen's pricing. Accordingly, the potential threat of entry has not been a sufficient competitive constraint on Aspen's pricing strategy and, as such, does not put into question Aspen's dominant position.

(70) With regard to the presence of countervailing buyer power, the Commission expressed concerns in its Preliminary Assessment that, in each of the Relevant Markets, buyers could in principle not switch to alternative medicines. As generic entry has only occurred recently and only in a few Relevant Markets, national authorities could not turn to generic producers for almost the entire Relevant Period. Under these circumstances, the Commission had concerns that there may not have been and may still not be sufficient countervailing buyer power to challenge, or offset, Aspen's market power in the Relevant Markets.

(71) Finally, the Commission found in its Preliminary Assessment that Aspen has been capable of profitably increasing prices generating very high profit margins and maintaining those prices and

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[43] The Commission notes that for some countries market share data is not available for all years. However, as Aspen's sales volumes have largely remained stable across these years in most of these markets and since Aspen may have been the only supplier on the market, the Commission has concerns that Aspen may have been holding very high market shares in these years as well.

[44] Furthermore, there are a few countries where, for some years and some of the Products, market shares dropped below 50%, either by volume or revenue or both. For each of those, the Preliminary Assessment analysed the relevant circumstances in light of the results of the market investigation, including the following: first, in certain countries, Aspen's market share remained, at least for a number of the other years, at very high levels (above the 50% threshold). Secondly, in several countries, the other market shares were held by parallel traders and their market shares tend to overstate their actual ability to act as a competitive constraint. Indeed, parallel traders sell products that they have obtained, directly or indirectly, from Aspen and/or its distributors. Parallel traders are thus entirely dependent on whether, to what extent and at which prices Aspen supplies markets in low-price Member States. Thirdly, even in periods when Aspen held a market share below 50%, it maintained throughout the Relevant Period very high profits that would have been eroded under conditions of effective competition. Each of these circumstances suggests market power of Aspen and contributed, together with the reasons summarised in Recitals (67)-(71), to the Preliminary Assessment's conclusion that Aspen may have been dominant in these countries throughout the Relevant Period, as mentioned in paragraph (72).

margins over significant periods. This is in itself a strong indication of a dominant position, because it reflects the power to behave to an appreciable degree independently of competitors and customers and ultimately of consumers. Had there been effective competition, it would over the years have eroded away Aspen's high prices and profits.

(72) In light of the considerations summarised in the Recitals (66) to (71), the Commission expressed concerns in its Preliminary Assessment that on all or most of the Relevant Markets for melphalan IV, melphalan oral, mercaptopurine, chlorambucil, busulfan oral and tioguanine, Aspen may have held a dominant position within the meaning of Article 102 TFEU during at least parts of the Relevant Period and may continue to do so.[45]

4.6. Practices raising concerns

(73) In its Preliminary Assessment, the Commission assessed Aspen's pricing practices in relation to the Products and reached the preliminary conclusion that Aspen may have abused its dominant position by imposing unfair prices pursuant to Article 102(a) TFEU in the form of excessive prices.

(74) The Commission's assessment followed the framework of analysis set out by the Court of Justice in its judgment in the *United Brands* case. The different steps of this assessment are described in Sections 4.6.3-4.6.4, after having recalled in Section 4.6.1 the applicable legal principles and described in Section 4.6.2 the findings in the Preliminary Assessment concerning Aspen's strategy and measures to implement high price increases.

4.6.1 Legal principles

(75) Article 102 TFEU prohibits as incompatible with the internal market any abuse of a dominant position insofar as it may affect trade between Member States. An abuse may consist, in particular, in directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions (Article 102(a) TFEU).

(76) One form of an unfair pricing abuse is the charging of excessive prices. Excessive pricing concerns, in essence, the extraction of excessive profits by a dominant undertaking by imposing particularly high and unfair prices on its customers, which cannot be explained by any legitimate considerations.

(77) The prohibition for dominant undertakings of exploiting customers through unfair prices as a primary example of an abuse in Article 102(a) TFEU reflects the goal to protect customers from direct harm.

4.6.1.1. Special responsibility of dominant undertakings

[45] This finding concerns the following markets where Aspen is selling the Products: melphalan IV: Austria, Belgium, Czechia, Estonia, France, Germany, Greece, Ireland, Lithuania (until FY2015), the Netherlands, Norway, Portugal, Poland, Slovakia, Slovenia, Spain, Sweden and the United Kingdom; melphalan oral: Austria, Belgium, Czechia, Estonia, Finland, France, Germany, Greece (except for FY2013, FY2016 and FY2018), Hungary (only for FY2012 to FY2014), Ireland, Latvia, Lithuania, the Netherlands, Norway, Poland, Portugal (except for FY2014 and FY2016 to FY2018), Romania, Slovenia, Slovakia, Spain, Sweden and the United Kingdom; mercaptopurine: Austria, Belgium, Bulgaria, Czechia, Denmark (until FY2016), Estonia, France, Germany, Greece (until FY2014), Ireland, Lithuania, the Netherlands, Norway, Portugal (until FY2014), Romania, Spain, Slovenia, Sweden and the United Kingdom; chlorambucil: Austria, Belgium, Bulgaria, Czechia, Denmark (until FY2015), Estonia, Finland, Greece, Ireland, Lithuania, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom; busulfan: Austria, Belgium, Czechia, Denmark, Estonia, France, Germany, Ireland (until FY2015), Lithuania, the Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden and the United Kingdom; tioguanine: Austria, Belgium, Bulgaria, Czechia, France, Germany, Ireland (until FY2014), Latvia (until FY2013), Lithuania (until FY2017), Norway, Poland, Portugal (until FY2016), Slovakia, Spain, Sweden and the United Kingdom.

(78) According to well-established case-law, undertakings in a dominant position have "a special responsibility"[46] and "may be deprived of the right to adopt a course of conduct or take measures which are not in themselves abuses" .[47]

(79) "[T]he actual scope of the special responsibility imposed on a dominant undertaking must be considered in the light of the specific circumstances of each case which show that competition has been weakened."[48] The Court of Justice has held that abuse is an objective concept[49] and that conduct may be an abuse "regardless of the means and procedure by which it is achieved", even "irrespective of any fault".[50]

4.6.1.2. Excessive pricing as a form of unfair prices

(80) Concerning unfair pricing in the form of excessive pricing, the Court of Justice considered in the *United Brands* judgment that a price is unfair when a *"dominant undertaking has made use of the opportunities arising out of its dominant position in such a way to reap trading benefits which it would not have reaped if there had been normal and sufficiently effective competition."*[51] In that case, *"a price which is excessive because it has no reasonable relation to the economic value of the product supplied would be such an abuse"*.[52]

(81) Furthermore, the Court has emphasised that different methods can be used to determine whether a price charged by a dominant undertaking is excessive and unfair and, therefore, abusive.

(82) In *United Brands,* the Court set out and explained one such method which consists of a two-step (limbs) analysis. The first limb examines the excessiveness of profits by determining *"objectively" [...] "whether the difference between the costs actually incurred and the price actually charged is excessive"* ('Limb 1'). The second limb analyses the unfairness of the price (that has been found to lead to excessive profits) by assessing *"whether a price has been imposed which is either unfair in itself or when compared to competing products"* ("Limb 2").[53] The Court has confirmed that it is sufficient to demonstrate that one of the two alternatives of Limb 2 is satisfied to establish that a price is abusive pursuant to Article 102(a) TFEU.[54]

(83) In *United Brands*, the Court of Justice emphasised that also other methods may be valid to establish an unfair pricing abuse.[55] Those other methods include in particular comparator tests. As summarised by Advocate General Wahl in his Opinion in case *AKKA/LAA*, comparisons of prices across competitors, between geographic markets by the same or other undertakings, or by the same undertaking at different points in time can be carried out.[56]

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46 Judgment of the Court of Justice of 2 April 2009, *France Telecom v Commission,* C-202/07P, EU:C:2009:214, paragraph 105; Judgment of the Court of Justice of 9 November 1983, *Nederlandsche Banden-Industrie Michelin v Commission*, 322/81, EU:C:1983:313, paragraph 57.

47 Judgment of the Court of First Instance of 17 July 1998, *ITT Promedia v Commission,* T-111/96, EU:T:1998:183, paragraph 139; Judgment of the Court of First Instance of 9 September 2009, *Clearstream Banking AG and Clearstream International SA v Commission,* T-301/04, EU:T:2009:317, paragraph 133.

48 Judgment of the Court of Justice of 16 March 2000, *Compagnie maritime belge transports a.o. v Commission,* C-395/96 P and C-396/96 P, EU:C:2000:132, paragraph 114; Judgment of the Court of Justice of 14 November 1996, *Tetra Pak v Commission,* C-333/94 P, EU:C:1996:436, paragraph 24.

49 Judgment of 16 July 2015, *Huawei Technologies Co. Ltd.*, C-170/13, EU:2015:477, paragraph 45.

50 Judgment of 21 February 1973, *Europemballage and Continental Can v Commission*, 6/72, EU:C:1973:22, paragraphs 27 and 29; Judgment of the Court of First Instance of 12 December 2000, *Aéroports de Paris v Commission,* T-128/98, EU:T:2000:290, paragraph 170.

51 Case C-27/76 *United Brands v Commission,* paragraph 249.

52 Case C-27/76 *United Brands v Commission,* paragraph 250.

53 Case C-27/76 *United Brands v Commission,* paragraphs 251- 252.

54 Order of the Court of Justice of 25 March 2009, *Isabella Scippacercola and Ioannis Terezakis v Commission,* C-159/08 P, EU:C:2009:188, paragraph 47.

55 For example, Case C-27/76 *United Brands v Commission*, paragraph 253: "*other ways may be devised - and economic theorists have not failed to think up several - of selecting the rules for determining whether the price of a product is unfair.*"

56 Opinion of Advocate General Wahl of 6 April 2017, *Autortiesību un komunicēšanās konsultāciju aģentūra / Latvijas Autoru apvienība v Konkurences padome,* Case C-177/16, EU:C:2017:286, paragraph 19 and cited case-law.

(84) Moreover, in Sirena, the Court held more generally that "although the price level of the product may not of itself necessarily suffice to disclose such an abuse, it may, however, [...] if it is particularly high, be a determining factor."[57]

(85) Where different methods of assessing whether a price is unfair within the meaning of Article 102(a) TFEU can be envisaged, the Court has recognised that it falls on the competition authority to select the adequate method and *"to define its framework"* in a specific case. In particular, it *"should be borne in mind that* [...an] *authority has a certain margin of manoeuvre and that there is no single adequate method.*"[58] With respect to the method selected, what matters is that the method itself *"must be considered valid*".[59]

(86) In the Preliminary Assessment, the Commission applied the two-limb framework set out by the Court of Justice in its *United Brands* judgment. As shown in Section 4.6.3, the Preliminary Assessment analysed, under Limb 1, the difference between the costs incurred and the prices charged and the excessiveness of the resulting *profits.* As shown in Section 4.6.4, the Preliminary Assessment analysed, under Limb 2, the unfairness of Aspen's *prices.* Section 4.6.2 describes the findings in the Preliminary Assessment concerning Aspen's strategy to increase the price of the Products and its implementation.

4.6.2 Aspen's strategy and measures to implement high price increases

4.6.2.1. Aspen's strategy of high price increases

(87) In the Preliminary Assessment, the Commission made the following findings. In 2011, after taking over the management of the Products – which were profitable on a portfolio level across the EEA – Aspen analysed them with the help of Global Value Dossiers. Those dossiers showed that patients depended on the medicines and had basically no substitutes in Europe. Against this background, because Aspen's *"key lever [is] in almost all the markets with the exception of Germany there is no replacement on the products targeted*"[60] and because of the possibility of extraordinary financial gains,[61] Aspen decided to increase in the EEA the pricing of its oncologic portfolio *"looking at a big push to increase the pricing on the oncolytic range"*.[62]

(88) Aspen implemented this strategy, even though it was met with strong concerns from within Aspen and from Aspen's distributors. [Aspen employee] expressed serious concerns about such a strategy: *"this is totally unrealistic in today's environment"; "who ever came up with these numbers has no connection with the reality of the pharmaceutical market in Europe"*.[63]

(89) The Preliminary Assessment found that Aspen devised a pan-European strategy to implement and to achieve the price increases. It included a number of measures aimed at overcoming the likely resistance of ministries of health or pricing and reimbursement authorities to the price increases.

4.6.2.2. Threats of de-listings and withdrawals, and actual de-listings

(90) A direct measure to overcome the resistance of national pricing and reimbursement authorities against the requests of high price increases by several hundred percent were threats to de-list the Products or to withdraw the Products from the market.

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57 Judgment of the Court of Justice of 18 February 1971, *Sirena vs Eda Srl and Others (Sirena),* C-40/70, EU:C:1971:18, paragraph 17.

58 Judgment of the Court of Justice of 14 September 2017 *in Autortiesību un komunicēšanās konsultāciju aģentūra / Latvijas Autoru apvienība v Konkurences padome*, C-177/16, EU:C:2017:689, paragraph 49.

59 Case C-177/16 *Autortiesību un komunicēšanās konsultāciju aģentūra / Latvijas Autoru apvienība v Konkurences padome*, paragraph 38.

60 Email dated 1 June 2011 from [Aspen employee] to [Aspen employee] regarding *"Onco Pricing opportunity priority – Europe".*

61 See email dated 1 June 2011 from [Aspen employee] to [Aspen employee] regarding *"Onco Pricing opportunity priority - Europe"* where *"every 5m we extract on this project is [...] an obvious no brainer [..]"* .

62 Email dated 26 May 2011 from [Aspen employee] to [Aspen employee] regarding *"Onco Pricing opportunity priority - Europe".*

63 Email dated 1 June 2011 from [Aspen employee] to [Aspen employee] regarding *"Onco Pricing opportunity priority – Europe".*

(91) De-listing is the removal of a medicine from the reimbursement list of the Member State concerned upon application of the pharmaceutical company. This entails the loss of the reimbursement status. Without reimbursement, patients risk having to pay for the cancer treatment costs themselves.

(92) A withdrawal on the other hand means that a medicine is "no longer commercialised in a Member State through all marketing channels".[64] Even though a medicine may still be supplied "under special license, and/or on a named patient basis and/or under like regulatory provisions",[65] national health authorities would then risk not being able to procure the required medicines unless they import the medicines at a foreign (possibly higher) price and depending on the availability on other markets. In any case, patient access to the medicines becomes more difficult, potentially less certain, and there is a risk of under-consumption due to the administrative burden of obtaining a special licence for each use.

(93) De-listing or withdrawing important medicines obviously poses a notable threat to access to those medicines for critically ill patients. The Commission found in its Preliminary Assessment that this was all the more serious, because Aspen understood well that patients were dependent on its medicines.

(94) The Commission furthermore found in its Preliminary Assessment that Aspen systematically applied this strategy throughout the EEA. For instance, it instructed [Aspen's distributors] to conduct the negotiations as follows: *"Again: the message is simple: The price is to be increased to the German level* [that is, list price]. *Take it or leave it. No other alternative. If the local MOH* [Ministry of Health] *doesn't accept the new price, we will either sell with no reimbursement or not supply at all. No place for negotiations. No time for reference to the other countries.*"[66]

(95) Aspen realised internally how effective this strategy had been with Member States: "we have pulled reimbursement in Romania and Czech (sic) and in both cases when we did this the MOH reverted and re-entered negotiations – the outcome in Czech (sic) is prices have been approved from [M]ay".[67] Therefore, Aspen concluded that this strategy would also work in other Member States: "I think the bottom line for finland as you eluded to if we don't get pricing we would not continue commercially – they can source from Denmark or Sweden where we have the [increased] prices" .[68]

(96) Aspen confirmed to the Commission[69] that during the Relevant Period delisting for the Products actually occurred in Bulgaria, Finland, Latvia, Portugal, Romania, Slovakia, Spain and the United Kingdom.[70] In addition, the Commission gathered evidence suggesting that Aspen threatened to de-list or to withdraw the Products also in several other Member States. In each case, with the exception of Spain and Portugal, the national pricing and reimbursement authorities eventually accepted that Aspen would increase the prices for the Products to Aspen's desired level.

4.6.2.3. Strategic sequencing of price increases to defeat the external reference pricing systems

(97) Aspen considered that due to external reference pricing (see Section 4.2.2), coordinating price increases across the EEA (including Russia) *"is very complex as everything is interlinked with each other"*.[71] Therefore, Aspen designed a "European Pricing Project" consisting of a strategic

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64 Aspen submission dated 11 May 2018, paragraph 10.

65 Aspen submission dated 11 May 2018, paragraph 10.

66 Email dated 23 April 2012 from [Aspen external consultant] to [Aspen's distributor] regarding *"the* […] *countries: Pricing and reimbursement COSMOS portfolio"*.

67 Email dated 27 February 2013 from [Aspen employee] to [Aspen employee] regarding *"COSMOS Finaland"*.

68 Email dated 27 February 2013 from [Aspen employee] to [Aspen employee] regarding *"COSMOS Finaland"*.

69 Aspen submission dated 5 February 2019, Table 1.

70 In the United Kingdom, Aspen did not strictly de-list the Products but "de-branded" them, which meant that Aspen took the Products out of a statutory pricing scheme and launched generic versions of the Products which would then enjoy free (and hence higher) pricing in the United Kingdom.

71 Email dated 12 February 2012 from [Aspen employee] to [Aspen employee] regarding *"Price increase project."*

sequencing of the price increases over three phases.[72] The aim was to defeat the purpose and effectiveness of the external reference pricing systems and to avoid parallel trade.

(98) Aspen started the price increase process in Germany because, under German law, Aspen had the freedom to unilaterally set new, increased list prices for the Products. A statutory claw-back applied in Germany with the aim of preventing increases of real net prices in Germany. However, these regulatory measures did not prevent Aspen from using the increased German list prices in its price increase applications in other Member States. As [Aspen employee] pointed out, the *"beauty about this is that the official German price is significant (sic) higher and can be used as reference in many other countries at this level."*[73] In 2013, 17 Member States actually used the German official list price as reference in their external reference pricing system.

(99) By strategically sequencing the price increase process, Aspen ensured that (list) prices that increased in one Member State were continuously referenced in other Member States, strategically influencing the price formation process in those other Member States. Moreover, through de-listings or withdrawals mentioned in Recital (96), Aspen could prevent that Member States would include low prices, which Aspen did not manage to increase, in their reference pricing basket.

4.6.2.4. Stock allocation system

(100) Another measure used by Aspen to implement its pan-European price increase strategy was to apply a stock allocation system. The stock allocation system essentially consisted of allocating quotas and, if necessary, withholding deliveries for the Products in some Member States. Through the stock allocation system, Aspen tried to ensure that following Aspen's price increases in some Member States, customers in those Member States would actually buy the Products only at the increased domestic prices and not at lower prices offered by parallel traders for imports from other Member States.

(101) Aspen's stock allocation system created situations where cancer patients risked not receiving the Products because Aspen did not want to *"remove the quote system until* [Aspen] [got] *the price increase finalised"*.[74] Aspen received, for instance, a complaint by a distributor, [quote from email relating to local supply].[75]

4.6.3 Excessive profits within the meaning of the United Brands judgment (Limb 1)

(102) The first of the two limbs set out by the Court of Justice in its *United Brands* ruling requires an analysis of whether the *profits* of the dominant undertaking are *excessive*. The following Section 4.6.4 sets out the Preliminary Assessment's assessment of the second limb of the analysis relating to the *unfairness of Aspen's prices.*

4.6.3.1. Principles for assessing Limb 1 and application in this case

(103) In the Preliminary Assessment, the Commission compared the *costs of production* to the *revenues* earned by Aspen with the Products and then assessed the excessiveness of the resulting profits.

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[72] Presentation dated 27 February 2012 entitled *"European Pricing Project"*, slide 16:
First phase: Aspen planned to initiate price increases *"in Germany, Denmark, Sweden and UK* [...]". In addition,*"[p]rices in several CEE countries need[ed] to be increased already during Phase I, to support price increases in other countries, i.e. Russia*";
Second phase: price increases in the EEA would follow in *"semi-reference countries like Italy, France,* Spain"; and
Third phase: price increases in the EEA would occur in *"statistical reference countries whereby it might be needed to pull product from reimbursement list [...]*".
For an overview of the chronology of Aspen's price increases for the Products in the EEA, see Annex 2.

[73] Email dated 15 September 2011 from [Aspen employee] to Aspen's marketing authorisation holder regarding *"UK Price increases?"*.

[74] See email dated 24 March 2014 from [Aspen employee] to [Aspen employee] regarding [issue of local supply].

[75] Email dated 13 May 2014 from [Aspen's distributor] to [Aspen employee] and [Aspen employee] regarding *"Aspen Portfolio: Alkeran & Purinethol Sales Trend"*. Given the lack of reaction by Aspen, [Aspen's distributor] repeated its concerns: [quote from email relating to local supply].

(104) There are various ways to assess the excessiveness of an undertaking's profits. In the present case, the Commission considered it most appropriate to carry out a comparison of Aspen's profitability with the profitability of a sample of other undertakings that, as explained further below, sell similar products and have a profile similar to Aspen ('Profitability Comparators'). The profitability of those other companies, during the same period, was then used to assess whether Aspen's profits have been significantly above industry levels.

(105) This comparison showed that the profitability levels achieved by Aspen in relation to the Products are much higher than the profitability levels of the Profitability Comparators in the Relevant Period. Accordingly, the Preliminary Assessment reached the preliminary conclusion that Aspen may have been earning excessive profits in the Member States identified below in Section 4.6.3.3.2.

4.6.3.2. The profits earned with the Products

(106) To assess the profitability of the Products under Limb 1, the Commission has identified the relevant production costs and revenues for each of the Products. It has then calculated the profitability under two profit metrics, namely (i) gross margin and (ii) Earnings Before Interest, Tax, Depreciation and Amortisation ('EBITDA') margin.

(107) As explained in Recitals (122) to (126), by applying both profitability metrics the Preliminary Assessment established that Aspen's profits earned with the Products have been very high throughout the period FY2013 to FY2019.

4.6.3.2.1. Costs associated with the Products

(108) The Commission has reviewed all of Aspen's accounting and financial data relating to the Products during the Relevant Period and, on that basis, identified the Products' costs of production.

(109) The Commission has taken into account direct costs and an appropriate amount of Aspen's indirect costs attributable to the Products. Direct costs are all costs incurred in the production, supply and distribution of the Products, which can be directly attributed to their sales.[76] Indirect costs are common costs (for example, operating costs) that Aspen incurred in the supply of more than one product (including the Products).[77]

(110) Aspen submitted that some of the operating costs incurred by its global and European subsidiaries represented indirect costs that would need to be attributed to the Products. The Commission assessed which part of those indirect costs should be accepted as attributable to the Products.

(111) There are various methods that may constitute valid possible approaches for allocating indirect costs in cases concerning pricing abuses. In the present case, the Commission considered methods base on revenue, volume and cost of goods sold ('COGS')[78] for the allocation of indirect costs.

(112) A revenue-based allocation attributes the indirect costs of an undertaking in proportion to its actual revenues. This means that if an undertaking generates, for example, 10% of its revenues with the investigated products, 10% of its total indirect costs would be allocated to the investigated products. In a case of suspected excessive pricing, a revenue-based allocation is, therefore, likely to increase the share of indirect costs attributed to the excessively priced products simply because they are excessively priced. This would distort significantly the calculation of profitability. Accordingly, the Preliminary Assessment did not consider such allocation mechanism appropriate in the case at hand.

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[76] Direct costs for the Products included, as per Aspen's accounts, the sum of cost of goods sold, bad debt, and costs related to logistics and distribution.

[77] These included, for example, operating costs related to employees of the finance and legal departments and head office overheads.

[78] COGS means the direct costs of producing the goods sold by a company. COGS include costs of the material and labor directly used to create the good and costs of purchasing a good from a third party supplier. COGS exclude indirect expenses (such as distribution costs or sales force costs).

(113) A volume-based allocation attributes indirect costs in proportion to the actual volumes of each of the Products sold by Aspen during the Relevant Period. A volume-based allocation can, in principle, be appropriate in cases concerning suspected price abuses. However, due to the heterogeneity of Aspen's products, the comparability of the relevant volume units across Aspen's business may be limited. Consequently, the Preliminary Assessment considered that attributing indirect costs solely based on volumes was not the most appropriate option for the purpose of this Decision.

(114) A COGS-based allocation attributes indirect costs in proportion to the actual COGS reported by Aspen for each relevant activity during the Relevant Period. The Preliminary Assessment considered this allocation method as a more appropriate basis for assessing the Products' profitability in the present case. This is because attributing indirect costs based on the Products' COGS can partially account for the heterogeneity across different products and is not affected by the specific circumstances of the suspected infringement contrary to a revenue-based allocation.

(115) Where the data available did not fully allow a COGS-based allocation, the Preliminary Assessment supplemented the COGS-based allocation with a volume-based allocation.[79]

4.6.3.2.2. Revenues generated through the Products

(116) For the Preliminary Assessment, the Commission reviewed Aspen's accounting and financial data and, on that basis, computed the Products' revenues. Revenues are the net sales by Product and Member State, as retrieved from Aspen's accounts. Net sales are gross sales minus certain expenditures, including wholesale discounts, rebates, promotions and returns.

4.6.3.2.3. Calculation of the Products' profits

(117) The Preliminary Assessment calculated the profitability of each Product by subtracting the sum of total direct and indirect costs attributable to each Product from the relevant revenues.

(118) As a general point, there are several profitability measures that can, in principle, be suitable to assess suspected price abuses, depending on the factual circumstances of each case. These include, in particular, gross margins, EBITDA margins and EBIT margins (also known as operating profit margins). In the present case, the Commission has focused on two measures of profitability, namely gross margins (that is net sales minus direct costs, and thus not considering indirect costs) and EBITDA margins. EBITDA margin is a net profitability measure that takes into account all direct costs and all indirect costs, with the exception of depreciation and amortisation costs (that cover impairment costs, which are thus also excluded). The Preliminary Assessment used EBITDA margin as the main profitability measure to assess the profitability of the Products, since it accounts for a broader set of costs than gross margins, and therefore provides a more complete picture of the costs required to carry out a given economic activity.

(119) In light of the specific circumstances of this case, the Preliminary Assessment did not base its assessment of profitability on EBIT. In general, EBIT are often also a suitable profitability measure, since they, as EBITDA, capture the net profitability of a firm.

(120) However, in certain circumstances, price remedies based on an EBITDA profitability assessment provide a more reliable basis for the implementation. This is the case, because EBIT margins (as recorded in the accounts of companies) are directly affected by how an undertaking may decide to

[79] The Commission requested from Aspen aggregated COGS data for all global and regional entities of Aspen that were involved in the supply of the Products and hence may have incurred relevant indirect costs. Aspen provided data on the global and EEA level for a number of products but stated that COGS data at regional or country level were either only partially available or not reliable for all the relevant years. To deal with the partial unavailability of reliable COGS data at regional and country level, the Commission used a volume-based allocation methodology where needed.

treat in its accounts depreciation, amortisation and impairment charges.[80] Measures of accounting profitability based on EBIT may thus be subject to large one-off accounting charges (for example one-off impairment costs). This is particularly relevant in this case, given that a large share of Aspen's assets is recorded as intangible assets of indefinite duration (subject to regular impairment tests). The Preliminary Assessment noted that Aspen had in fact reported an accounting impairment cost in FY2019 (but not during the remainder of the Relevant Period), due to perceived pricing pressures in Europe from alleged increasing competition. The presence of this impairment charge leads to a significant one-off change in its reported EBIT (but not to its EBITDA) in FY2019.[81] In view of this volatility in the present case, and given the forward-looking nature of remedies, the Commission focused its Preliminary Assessment on Aspen's EBITDA.

(121) In light of the considerations summarised in Recitals (118) to (120), in order to assess the excessiveness of Aspen's profits with the Products, the Commission has computed EBITDA margins both for the Products under investigation and for a group of companies that sell similar products and have broadly a similar profile to Aspen (for Profitability Comparators, see Section 4.6.3.3.1). This comparison is robust to different accounting treatments of depreciation, amortisation and impairment charges across firms.

4.6.3.2.4. Aspen earned very high profits with the Products

(122) Table 1 below sets out the Commission's profit calculations for the Products during the period FY2013 to FY2019.

(123) In terms of gross profits, Aspen earned with all Products considered together total profits of [above EUR 200 million] in the EEA during the period from FY2013 to FY2019. This amount is equivalent to a gross margin of [80-90]% on Aspen's net sales of approximately EUR […].

(124) In terms of EBITDA profits, Aspen earned with all Products taken together a profit of [above EUR 200 million], equivalent to a margin of [80-90]% during the period from FY2013 to FY2019 on Aspen's net sales of approximately EUR […].

Table 1: Profitability by Product during the period FY2013 to FY2019, EEA (excluding Italy)

Product	Net Sales (€m)	Gross Profits (€m)	Gross Margins[82]	EBITDA Profits (€m)	EBITDA Margins
Alkeran (IV)	[…]	[…]	[80-90]%	[…]	[80-90]%
Alkeran Oral	[…]	[…]	[80-90]%	[…]	[70-80]%
Lanvis	[…]	[…]	[60-70]%	[…]	[40-50]%
Leukeran	[…]	[…]	[80-90]%	[…]	[70-80]%
Myleran	[…]	[…]	[80-90]%	[…]	[80-90]%
Purinethol	[…]	[…]	[90-100]%	[…]	[80-90]%
Total	**[…]**	**[…]**	**[80-90]%**	**[…]**	**[80-90]%**

(125) As Table 2 below demonstrates, gross margins and EBITDA margins increased sharply as of FY2013, and then remained at very high levels throughout the period between FY2014 and FY2019. According to the information available to the Commission, there are no indications that

[80] The term impairment refers to a reduction in the value of an undertaking's asset. When testing an asset for impairment, the total expected profit, cash flow, or other benefit for that specific asset is compared with its current book value. If the asset's book value exceeds the asset's future cash flow or benefit, the difference between the two is written off and the asset's book value is reduced on the undertaking's balance sheet.

[81] See Aspen Annual Financial Statement for FY2019, paragraph 40.

[82] Gross margins and EBITDA margins in the Preliminary Assessment represent a percentage of net sales.

the price levels corresponding to those margins have materially changed since the end of Aspen's FY2019 (end of June 2019).

Table 2: Profitability by year, all Products EEA (excl. Italy), FY2012 to FY2019

Year	Net Sales (€m)	Direct Costs (€m)	Total Costs (€m)	Gross Profits (€m)	Gross Margins	EBITDA (€m)	EBITDA Margins
2012	[…]	[…]	[…]	[…]	[60-70]%	[…]	[40-50]%
2013	[…]	[…]	[…]	[…]	[80-90]%	[…]	[70-80]%
2014	[…]	[…]	[…]	[…]	[80-90]%	[…]	[70-80]%
2015	[…]	[…]	[…]	[…]	[80-90]%	[…]	[80-90]%
2016	[…]	[…]	[…]	[…]	[80-90]%	[…]	[80-90]%
2017	[…]	[…]	[…]	[…]	[80-90]%	[…]	[80-90]%
2018	[…]	[…]	[…]	[…]	[80-90]%	[…]	[80-90]%
2019	[…]	[…]	[…]	[…]	[80-90]%	[…]	[80-90]%

(126) This evidence shows that by both measures of profitability, the Products have persistently earned very high profits during a period spanning seven years (FY2013 to FY2019)[83] both in absolute terms and when compared with the profitability levels of similar businesses in the industry (as it will be shown below).[84] This is a first indication that the profits Aspen have been earning with the Products are excessive.

4.6.3.3. Assessment of excessiveness

4.6.3.3.1. Profitability of comparator companies

(127) When assessing the excessiveness of the Products' profit levels against a benchmark, the Commission's Preliminary Assessment accounted for the fact that undertakings need to earn a reasonable profit margin and, in particular, a rate of return of capital employed ('ROCE'; see also Recital (154)). Indeed, in markets working under conditions of *"normal and sufficiently effective competition"*,[85] undertakings are active in the market, because they can expect to earn a financial return that is sufficient to compensate their investment.

(128) Depending on the circumstances of each case, different methods may be suitable and used to determine a reasonable rate of return for the purposes of establishing a benchmark to be used in assessing the potential excessiveness of profit levels. In the present case, the Commission analysed the profitability of a sample of undertakings that are similar to Aspen and for which the Commission has no indications that they do not operate under conditions of sufficiently effective competition.

(129) Firstly, the Commission in particular identified a set of companies based on a number of objective criteria. Based on IQVIA[86] data for the period 2017-2018, the Commission identified all companies whose combined sales cumulatively fulfil the following criteria: (i) at least EUR 1 million revenues were generated through either off-patent branded or generic products,[87] (ii) at least 70% of the total

[83] For the period before FY2013, see Recital (142).

[84] See Table 4. The Products at a portfolio level earned gross margins in excess of [80-90]% in the period FY2013 to FY2019, whereas the profitability level of the industry was 54%. In terms of EBITDA margins, the Products overall earned a margin of [80-90]% in the period FY2013 to FY2019, which was significantly above the 23% EBITDA margin of the industry.

[85] See Case C-27/76 *United Brands v Commission*, paragraph 249.

[86] IQVIA is a company providing healthcare data.

[87] Off-patent branded and generic products do not enjoy any intellectual property protection and, accordingly, have the common feature that in competitive markets they generally do not enjoy high returns (as they do not benefit from market exclusivity).

revenues reported in IQVIA were earned by either off-patent branded or generic products; and (iii) at least EUR 100,000 was earned by products listed in the 'Antineoplastics', ATC-2 category L1.[88] By applying those criteria, the Commission ensured that the Profitability Comparators sell mainly generic or off-patent branded medicines with at least a material part of their revenues stemming from medicines that are similar to the Products in terms of active substance.

(130) Secondly, the Commission collected data on the Profitability Comparators for the two profitability measures described in Recital (118), namely gross margins and EBITDA margins, for the period 2013-2018.[89]

(131) Table 3 sets out the median figures for each of those profitability measures, expressed in each case as a percentage of net sales.

Table 3: Profitability measures for Profitability Comparators (expressed as % of sales)

	Gross Margin	**EBITDA Margin**
Median	54%	23%

(132) While the median EBIDTA margin of the Profitability Comparators[90] provides a useful input to assess whether the difference between the costs actually incurred and the prices actually charged by Aspen was excessive, the Commission does not consider that such median profitability (or in general, any average profitability measure) in itself determines the threshold above which profits should be considered excessive. It is in fact inherent in any median, or average profitability, that many market participants earn margins that are above the median or the average,[91] as it was also the case for the Profitability Comparators. Therefore, not every deviation from the median or average profitability in an industry results directly in excessiveness within the meaning of Limb 1 of the *United Brands* judgment.

(133) Against this background and for the additional reasons set out in this Recital and Recitals (134) to (137), the Preliminary Assessment found that the difference between Aspen's costs actually incurred and Aspen's prices actually charged should be considered excessive within the meaning of Limb 1 only, if Aspen's prices earned a profit margin that *significantly exceeded* the median of the Comparators.

(134) Moreover, costs may fluctuate in real life markets and companies need a certain margin of commercial manoeuvre to adjust their prices before their conduct amounts to an abuse of

[88] The Anatomic-Therapeutic-Chemical Classification (ATC system) of the World Health Organisation classifies all medical molecules and molecule combinations for medical use in the human body into a five-layer hierarchical system. Level 2 (ATC-2) corresponds to the classification of the Products. The Commission considers that these criteria ensure that the set of Comparators is sufficiently large, features portfolios that are dominated by off-patent branded and/or generic medicines and targets cancer patients (receiving treatments with antineoplastics). Off-patent branded products include all products that, according to IQVIA, were launched at the latest by the last quarter of 2005 and hence were highly unlikely to be under patent protection.

[89] The sample of Profitability Comparators consists of companies for which profitability data was available on the Bloomberg database for the period 2013 to 2018. The list of companies with available data was manually verified. As a result of this verification exercise, three companies were excluded from the sample, either because they were not suppliers but merely distributors of medicines in the ATC-2 category L1, or because their products in the ATC-2 category L1 had a protected "orphan" status. "Orphan" status is granted as incentive and reward for developing medicines treating rare diseases and is typically linked to an extended period of marketing exclusivity. Orphan medicines are therefore not comparable to off-patent branded and generic products that do not enjoy marketing exclusivity. The Profitability Comparator data set used consists of 23 companies corresponding to 66 observations of gross margins and 108 observations of EBITDA; 'observation' refers to each profitability data point (gross margin and EBITDA) available for a single undertaking and year.

[90] The median value of a data series is the value that separates the higher half of the data sample from the lower half (that is to say, the "middle" value). The median is an adequate measure in this case, as it is not affected by the presence of outliers.

[91] In case of the median, half of the market participants earn more than, or at the level of, the median.

dominance. A certain fluctuation of prices is often part of the normal competitive process.[92] However, in this case, the Preliminary Assessment found that Aspen's price increases were clearly not part of such a normal competitive process (see further Recitals (161) to (201)).

(135) Furthermore, the availability of data, assumptions on cost allocations or choices regarding methodology may have a certain impact on the precision of the profit calculations, which should be accounted for.

(136) Also for these reasons, only profits significantly exceeding the median can be considered excessive.

(137) In general, what constitutes an appropriate benchmark to determine whether a profit (and price) level is excessive and which deviation from that benchmark is sufficiently significant depends on the specific circumstances of each case and, in particular, the products and markets concerned.

(138) Taking into account the considerations summarised in Recitals (132) to (136) ensures that only such profit (and price) levels are caught by the prohibition in Article 102(a) TFEU, possibly leading to fines, that can safely be deemed to amount to an exploitative abuse. The foregoing considerations are reflected and accounted for in the cost-plus methodology relied on in the Preliminary Assessment and presented in the next Section.

4.6.3.3.2. Excessive profits in view of the profitability of comparators

The cost-plus level as a measure to assess excessiveness

(139) To determine whether Aspen's profits were excessive, the Commission's Preliminary Assessment compared Aspen's actual prices for the Products to the Products' total costs increased by a "plus" element (the 'cost-plus level'). The "plus" is the proxy for a reasonable profit margin under competitive conditions and is based on the median measure of the Profitability Comparators' EBITDA observations, in other words, the 23% EBITDA margin (the 'Comparator Profitability'). Only a significant excess over that cost-plus level can be deemed excessive within the meaning of Limb 1 of the *United Brands* judgment.

Excessiveness of Aspen's profits at EEA level

(140) Table 4 shows the result of the comparison between the actual prices of the Products and the cost-plus level (that is, the actual production costs incurred by Aspen for each Product increased to account for the median EBITDA margin) for each Product individually and for the Products overall at EEA level.[93] More specifically, the value figure (in EUR million) and the percentage figure, in the second and third column in Table 4, show by how much the revenues generated by Aspen with the Products exceeded the revenue levels that would, according to the Preliminary Assessment, have been required to earn a reasonable profit margin, based on the Profitability Comparators. It is therefore a measure of excessive profits.

[92] For more general considerations concerning fluctuations of prices in the context of excessive pricing in pharmaceuticals, see European Commission's submission to the OECD roundtable on Excessive Pricing in Pharmaceuticals, 28 November 2018, available at https ://one.oecd.org/document/DAF/COMP/WD(2018)112/en/pdf.

[93] The "cost-plus" level of revenues is obtained by dividing total costs by 0.77, that is one minus the Comparator Profitability (23% EBITDA margin).

Table 4: "Cost-plus" analysis by Product, FY2013 to FY2019, EEA (excluding Italy)

Product	"Cost-Plus" (€m)	Excess over "Cost-Plus" (€m)	% Excess over "Cost-Plus"
Alkeran (IV)	[…]	[…]	[300-320]%
Alkeran (Oral)	[…]	[…]	[160-180]%
Lanvis	[…]	[…]	[40-50]%
Leukeran	[…]	[…]	[200-220]%
Myleran	[…]	[…]	[260-280]%
Purinethol	[…]	[…]	[400-420]%
Total	**[…]**	**[above EUR 200 million]**	**[280-300]%**

(141) The results in Table 4 show that the Products as a whole generated profits for Aspen exceeding the cost-plus level by [above EUR 200 million] in the period FY2013 to FY2019. This translates into a percentage excess over cost-plus of [280-300]%. That means that on top of a reasonable return, Aspen earned additional profits roughly three times the level of cost-plus. As regards individual Products, the percentage excess over cost-plus exceeds [380-400]% in the case of Purinethol and [280-300]% in the case of Alkeran IV. For three other Products, the excess over cost-plus is in the range of approximately [160-180]% to [260-280]%. There is only one product (Lanvis) for which the percentage excess over cost-plus is below [90-100]%, but still significant, namely [40-50]%.

(142) Table 5 provides an overview of the cost-plus analysis for all Products on an annual basis over time, including FY2012, that is, the year when Aspen started to implement the first price increases. As Table 5 illustrates, the percentage excess over cost-plus increased sharply as of FY2013 and remained at a very high level and was stable from FY2014 to FY2019. Given the Products' profitability margins in FY2012, the Commission's Preliminary Assessment found that it cannot be excluded that the Products' profits may have been excessive already in FY2012, at least in certain Relevant Markets. However, as Aspen's price increases had only started to be implemented and had not fully materialised in FY2012,[94] the Commission focused its assessment of excessiveness on FY2013 and the following years.

Table 5: Profitability and "cost-plus" analysis by year, all Products EEA (excl. Italy), 2012 to 2019

FY	2012	2013	2014	2015	2016	2017	2018	2019
% Excess over "Cost-Plus"	[30-40]%	[200-220]%	[240-260]%	[280-300]%	[280-300]%	[300-320]%	[340-360]%	[320-340]%

(143) On that basis, when looking at the average profitability at Product level and the Products' total profitability over time at portfolio level in the EEA, the Commission's Preliminary Assessment

[94] Price increases had been approved only at the end of FY2012 (May to July 2012) in Estonia, Germany, Latvia, Lithuania and Poland.

expressed concerns that Aspen made profits significantly exceeding industry levels (as expressed through the Comparator Profitability) from FY2013 to FY2019.

Excessiveness of Aspen's profits per Product in the different Member States

(144) The Preliminary Assessment found that, during the period FY2013 to FY2019, Aspen earned revenues exceeding the cost-plus level with each of the Products in almost all of the Relevant Markets, with just a few exceptions. In most Relevant Markets, each of the Products has earned persistently levels of excess profits very significantly over the cost-plus level. In other Relevant Markets, the Products have earned lower but still significantly high profits, such that the Commission had concerns that they are excessive.

(145) The overview results of the cost-plus analysis at the level of each Relevant Market, as found in the Preliminary Assessment, are summarised in Recitals (146) to (152), while the underlying data is set out in Annex 1.

Alkeran IV

(146) The average excess of Aspen's profits over the cost-plus level across all the 22 Member States where Aspen has been selling Alkeran IV during the period FY2013 to FY2019 was [300-320]%. This means that Alkeran IV was earning on average approximately [3-5] times higher revenues than those required to achieve the industry profitability level (as expressed through the Comparator Profitability). In 15 out of these 22 Member States[95], Alkeran IV earned over [280-300]% excess profit above the cost-plus level, with an excess over cost-plus reaching up to [600-620]% in Norway and [460-480]% in Lithuania. Only in one Member State – Poland – was Alkeran IV's profitability below the average profit levels in the industry (as expressed through the Comparator Profitability). Accordingly, in many of the Member States where Aspen sold Alkeran IV, it earned profits that significantly exceeded industry levels. These Member States represented the overwhelming majority of total sales of Alkeran IV during the period FY2013 to FY2019.

Alkeran Oral

(147) The average excess of Aspen's profits over the cost-plus level across all the 24 Member States where Aspen has been selling Alkeran Oral during the period FY2013 to FY2019 was [160-180]%. This means that Alkeran Oral was earning on average approximately [2-3] times higher revenues than those required to achieve the industry profitability level (as expressed through the Comparator Profitability). In 6 out of those 24 Member States[96], Alkeran Oral earned over [180-200]% excess profit above the cost-plus level, with an excess over cost-plus reaching up to [320-340]% in Greece and [240-260]% in France. Only in four Member States was Alkeran Oral's profitability below the average profit levels in the industry (as expressed through the Comparator Profitability).[97] Accordingly, in many of the Member States where Aspen sold Alkeran Oral, it earned profits that significantly exceeded industry levels. Those Member States represented the overwhelming majority of total sales of Alkeran Oral during the period FY2013 to FY2019.

Purinethol

(148) The average excess of Aspen's profits over the cost-plus level across all the 23 Member States where Aspen has been selling Purinethol during the period FY2013 to FY2019 was [400-420]%. This means that Purinethol was earning on average approximately [4-6] times higher revenues than those required to achieve the industry profitability level (as expressed through the Comparator

[95] Austria, Czechia, Denmark, Finland, Germany, Greece, Iceland, Ireland, Lithuania, Norway, Portugal, Slovakia, Slovenia, Sweden, United Kingdom.

[96] France, Germany, Greece, the Netherlands, Slovakia, United Kingdom.

[97] Cyprus, Estonia, Iceland, Latvia.

Profitability). In 9 out of those 23 Member States[98] , Purinethol earned over [380-400]% excess profit above the cost-plus level, with an excess over cost-plus reaching up to [900-920]% in Malta and [600-620]% in Sweden. Only in two Member States was Purinethol's profitability below the average profit levels in the industry (as expressed through the Comparator Profitability).[99] Accordingly, in many of the Member States where Aspen sold Purinethol, it earned profits that significantly exceeded industry levels. Those Member States represented the overwhelming majority of total sales of Purinethol during the period FY2013 to FY2019.

Leukeran

(149) The average excess of Aspen's profits over the cost-plus level across all the 25 Member States where Aspen has been selling Leukeran during the period FY2013 to FY2019 was [200-220]%. This means that Leukeran was earning on average approximately [2-4] times higher revenues than those required to achieve the industry profitability level (as expressed through the Comparator Profitability). In 10 out of those 25 Member States,[100] Leukeran earned over [180-200]% excess profit above the cost-plus level, with an excess over cost-plus reaching up to [340-360]% in Belgium and [320-340]% in the United Kingdom. Only in five Member States was Leukeran's profitability below the average profit levels in the industry (as expressed through the Comparator Profitability).[101] Accordingly, in many of the Member States where Aspen sold Leukeran, it earned profits that significantly exceeded industry levels. Those Member States represented the overwhelming majority of total sales of Leukeran during the period FY2013 to FY2019.

Lanvis

(150) The average excess of Aspen's profits over the cost-plus level across all the 22 Member States where Aspen has been selling Lanvis during the period FY2013 to FY2019 was [40-50]%. This means that Lanvis was earning on average approximately [1-2] times higher revenues than those required to achieve the industry profitability level (as expressed through the Comparator Profitability). In 8 out of those 22 Member States[102], Lanvis earned over [50-60]% excess profit above the cost-plus level, with an excess over cost-plus reaching over [80-90]% in Poland and Sweden. Only in five Member States was Lanvis' profitability below the average profit levels in the industry (as expressed through the Comparator Profitability).[103] Accordingly, in many of the Member States where Aspen sold Lanvis, it earned profits that significantly exceeded industry levels. These Member States represented the majority of total sales of Lanvis during the period FY2013 to FY2019.

Myleran

(151) The average excess of Aspen's profits over the cost-plus level across all the 20 Member States where Aspen has been selling Myleran during the period FY2013 to FY2019 was [260-280]%. This means that Myleran was earning on average approximately [3-5] times higher revenues than those required to achieve the industry profitability level (as expressed through the Comparator Profitability). In 10 out of these 20 Member States[104], Myleran earned over [180-200]% excess profit above the cost-plus level, with an excess over cost-plus reaching up to [540-560]% in the United Kingdom and [420-440]% in Belgium. Only in two Member States was Myleran's profitability below the average profit levels in the industry (as expressed through the Comparator Profitability).[105] Accordingly, in many of the Member States where Aspen sold Myleran, it earned

98 Austria, Belgium, Denmark, Iceland, Malta, the Netherlands, Portugal, Sweden, United Kingdom.
99 Bulgaria, Latvia.
100 Austria, Belgium, Finland, Germany, Greece, Lithuania, the Netherlands, Poland, Sweden, United Kingdom.
101 Bulgaria, Cyprus, Estonia, Malta, Portugal.
102 Austria, Bulgaria, Denmark, Germany, Poland, Portugal, Sweden, United Kingdom.
103 Belgium, Estonia, Latvia, Lithuania, Slovakia.
104 Belgium, Czechia, Denmark, Finland, Germany, the Netherlands, Norway, Slovakia, Sweden, United Kingdom.
105 Iceland, Portugal.

profits that significantly exceeded industry levels. Those Member States represented the overwhelming majority of total sales of Myleran during the period FY2013 to FY2019.

Preliminary conclusion

(152) The Preliminary Assessment reached the preliminary conclusion that Aspen may have been earning excessive profits with the Products in most Relevant Markets in the Relevant Period and may have continued to earn such profits. The Commission has no indications that profits have materially changed after the end of Aspen's FY2019. The Relevant Markets concerned cover the overwhelming majority of Aspen's overall revenues from these Products.

4.6.3.3.3. Aspen's claim that the price increases were necessary to recover its investment

(153) During the course of the investigation, Aspen claimed that the price increases implemented from mid-2012 were necessary to earn a sufficient return on its investment in the Products, in light of the acquisition price Aspen had paid to GSK.

(154) First, the Commission recognises that companies are entitled to make a reasonable rate of return, in order to cover their cost of capital. In fact, the Commission's preliminary assessment of the Products' profitability on the basis of a cost-plus analysis (as set out in Section 4.6.3.3.) accounts for a reasonable rate of return, in line with the industry's average performance, by adding a "plus" element to the costs based on the Comparator Profitability. That "plus" element allows recovering the costs of capital. In principle, no further recognition of the remuneration of the capital employed in the Products is therefore required.

(155) Second, the Commission looked at alternative methods to assess the excessiveness of Aspen's profits, allowing for a reasonable rate of return in the Products. The Commission considers that an alternative method could have been to directly compute the capital employed in the Products and the associated cost of capital (rather than inferring a reasonable rate of return from the Profitability Comparators). However, Aspen has not accounted for any specific tangible or intangible assets acquired by Aspen in connection with the Products.[106] This renders the identification of the underlying capital employed in the Products a complex exercise, which was in the present case not required given the clear concerns identified in the Limb 1 analysis in Sections 4.6.3.3.2. and 4.6.3.3.3.

(156) Third, the Commission also analysed whether the acquisition price paid by Aspen could be considered as a suitable proxy for the capital employed in the Products. However, the Commission found in the Preliminary Assessment that this was not the case for a number of reasons. As stated in Recital (155), Aspen has not identified in its accounts any specific tangible or intangible assets in connection with the Products. Instead, the acquisition price paid by Aspen is likely to reflect mainly the capitalised value of future expected profits from the Products (as opposed to the value of assets), as suggested also by Aspen's own 2009 evaluation. The acquisition price may therefore include positive economic profits that the original owner of the Products (GSK) would have expected to earn from the Products, over and above the level of profitability required to cover the cost of the capital employed in the Products. The relatively high accounting profitability of the Products at the time of the acquisition suggests that those economic profits are likely to have been a significant component of the overall acquisition price paid by Aspen to GSK.[107] Using the

[106] When acquiring the Products from GSK, Aspen did not record in its account any tangible assets, nor intangible assets of a finite duration (such as patents). Aspen instead recorded the entire business as an intangible asset of indefinite duration, subject to a periodic impairment test, which was similar to the treatment of goodwill. Similarly, Aspen did not identify any specific assets that would have a value outside the Products' business itself. This was consistent with the fact that the Products were part of a product portfolio with no physical manufacturing facilities and no patent-protected intellectual property.

[107] The portfolio of Products earned an EBITDA margin in excess of [40-50]% in FY2012 (that is, before the price increases were fully implemented across all the Relevant Markets by Aspen). This was above the Comparator Profitability (see Table 4).

acquisition price to measure the return on capital earned by Aspen (and hence the profitability of the Products) would therefore create a circularity problem, as the acquisition price itself is a function of the profits expected from the Products.[108]

(157) These considerations suggest that the acquisition price is likely to significantly overstate the value of the underlying assets (or capital) employed in the Products. Using the acquisition price to assess the return on the capital employed in the Products is in turn likely to significantly under-estimate the underlying profitability of the Products. Moreover, since the acquisition price should be interpreted as largely a transfer of expected future profits from GSK to Aspen, and not as the valuation of specific tangible or intangible assets acquired by Aspen, it would be also conceptually incorrect to treat the acquisition price as a relevant cost of production or cost of supplying the product, within the meaning of Limb 1 of the *United Brands* judgment.[109]

(158) Finally, even if the Commission were to consider the return on the acquisition price paid by Aspen as a proxy for the ROCE in the Products *(quod non)*, the evidence indicates that Aspen earned a very high return on its investment in the Products in light of the large price increases it implemented during (and shortly before) the Relevant Period. The return is several-fold greater than Aspen's cost of capital (which included both the cost of external capital and a return for equity holders to reward their invested capital based on market benchmarks).[110] The large difference between the return realised by Aspen and its cost of capital confirms the Commission's assessment of the excess profitability of the Products set out in Section 4.6.3.3. This preliminary conclusion is further reinforced by the fact that the return on Aspen's investment into the Products is likely to significantly underestimate the underlying profitability of the Products.

(159) In light of the considerations summarised in Recitals (153) to (158), in its Preliminary Assessment, the Commission reached the preliminary conclusion that the acquisition price paid by Aspen to GSK in 2009 for the Products should not be separately reflected in the assessment of the excessiveness of the profits earned by the Products.

4.6.3.4. Preliminary conclusion on Limb 1

(160) The Preliminary Assessment reached the preliminary conclusion that the Products may have been earning excessive profits during the Relevant Period and may have continued to earn such excessive profits given that the Commission had no indications that profit margins materially changed after the end of the FY2019.

4.6.4 Unfairness of Aspen's prices within the meaning of the United Brands judgment (Limb 2)

4.6.4.1. Principles for assessing Limb 2: unfairness

(161) According to the *United Brands* judgment, to be abusive, a price charged by a dominant undertaking must not only generate excessive profits (Limb 1) but the price must also be unfair (Limb 2).

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[108] This circularity problem implies, for example, that a business with significant expected profits may be incorrectly associated with a low computed return on capital employed, if the future expected profits manifest themselves in a high acquisition price and if the acquisition price itself is used as a proxy for the capital employed. For further references on the shortcomings of using acquisition prices or market valuations in the context of profitability assessment under competition law see: Mark Williams, 2007, "Excessive Prices" in The Pros and Cons of High Prices, Swedish Competition Authority; and OFT, 2003, "Assessing profitability in competition policy analysis", Economic Discussion Paper 6 (A report prepared by OXERA).

[109] For similar reasons, impairments of the value of past acquisitions (for example typically booked in accounts as impairments of goodwill) should not be taken into consideration as a relevant cost of production.

[110] Aspen's annual return on its investment in the Products (that is, the Internal Rate of Return) could be estimated at close to [40-50]%, well above the cost of capital used by Aspen in its initial evaluation of the acquisition ([10-20]%), which had been based on market benchmarks. Aspen's internal rate of return was even higher if one looked only at the period FY2013 to FY2019 (the return of capital was [50-60]% during this period, taking as a proxy for the capital employed the Present Value of earnings from the Products at pre-increase prices).

(162) Under the *United Brands* framework of analysis, the conclusion of whether a price is unfair can be reached in two alternative ways[111], either (i) the price is unfair in itself, or (ii) the price is unfair when compared to competing products.

(163) The Limb 2 unfairness analysis has the purpose of examining whether there may be legitimate reasons underlying the excessive profits identified under Limb 1, in particular reasons not yet reflected in the cost analysis in Limb 1.[112] For instance, the dominant undertaking's excessive profits could reflect, partially or entirely, superior efficiencies regarding the production or the selling of the products.[113] Similarly, a dominant undertaking may have taken risks, made investments, improved a product or innovated in a way that could render high profits, partially or entirely, a legitimate reward for pro-competitive efforts. It is important to note, however, that even these reasons do not legitimise the charging of a price at any high level. They have, however, to be given due consideration in the assessment of a potential unfairness.

(164) Once next to the excessiveness of profits under Limb 1 also the unfairness of a price under Limb 2 has been established, then it is clear that the *"dominant undertaking has ... reap[ed] trading benefits which it would not have reaped if there had been normal and sufficiently effective competition"*. And "[i]n *this case"*, as the Court of Justice explained, the prices have *"no reasonable relation to the economic value of the product[s] supplied*"[114]

4.6.4.2. Assessment of unfairness "in itself"

(165) To assess whether Aspen's prices are unfair in themselves, the Preliminary Assessment analysed whether Aspen had carried out any particular activity in relation to the Products (such as potential innovations or commercial risk-taking). It further considered the characteristics of the Products as medicines that had been off-patent for decades, but on which a number of cancer patients still depend. In addition, the Preliminary Assessment considered the stark disproportion between the (limited) increases in the costs of the Products and the (very high) price increases leading to a very high level of Aspen's profits and prices. Finally, the Preliminary Assessment considered the strategy and means that Aspen employed when implementing the high price increases.

(166) The Commission found in the Preliminary Assessment that there are no legitimate reasons underlying the level of Aspen's prices. Instead, evidence showed that Aspen's high profits originate from the exercise of market power which arises from a lack of effective competition.

4.6.4.2.1. No legitimate reasons underlying Aspen's high prices and excessive profits

(167) The examination of the justification of unfair pricing practices has to be particularly stringent in a context where customers are completely dependent on a product.[115]

The nature of Aspen's Products

(168) The Commission's investigation has shown that the Products are old, off-patent medicines on which cancer patients and health systems still depend.

(169) Aspen's Products lost their patent protection approximately 50 years ago. Patent law gives the innovator an exclusive right to the commercial exploitation of the invention for a certain period of time. This period of time compensates the originator for the innovative work. It also allows the

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111 See Order of the Court of Justice of 25 March 2009, *Isabella Scippacercola and Ioannis Terezakis v Commission*, C-159/08 P, EU:C:2009:188, paragraph 47.

112 The cost analysis of Limb 1 generally covers efforts reflected in costs linked to the production or the commercialisation of products, including efforts required to supply a medicine on the market, which requires meeting regulatory requirements or maintaining regulatory authorisations. These efforts may sometimes also include minor product adjustments or improvements.

113 See European Commission's submission to the OECD roundtable on Excessive Pricing in Pharmaceuticals, 28 November 2018, paragraph 11, available at: https://one.oecd.org/document/DAF/COMP/WD(2018)112/en/pdf

114 Case C-27/76 *United Brands v Commission*, paragraphs 249 and 250.

115 See also the Opinion of Advocate General Jacobs of 26 May 1989 in Case *Ministère public v Jean-Louis Tournier*, C-395/87, EU:C:1989:215, paragraphs 43, 65 and 66.

originator to recoup the significant investment costs for research and development. After patent expiry, those costs are deemed to have been recouped. Since the Products' patent protection had expired, it can be assumed that costs for research and development of the Products had already been recovered.

(170) Although Aspen's Products are old, they are nonetheless still important and life-prolonging medicines that are still widely used for the treatment of certain cancers. For some patient groups, the Products cannot be substituted. For example, Melphalan IV, Purinethol and Leukeran treat frail or elderly citizens or children. As one of its distributors pointed out to Aspen in 2011, before Aspen's price increases, the Products *"are for critically ill patients who are depending on it"* and *"there are no generics in Europe"*.[116] The dependency of patients and health systems on Aspen's products made demand for the Products highly inelastic, and the Products' customers vulnerable to exploitation.

No legitimate reasons underlying Aspen's high prices

(171) The Commission further found in the Preliminary Assessment that Aspen's prices and profits neither reflect any commercial risk-taking activity, nor innovation, nor investment, nor any material improvement regarding the Products.

(172) When Aspen acquired the Products from GSK in 2009,[117] the business and brands had been fully established and the portfolio was very profitable. In 2012, the portfolio made profits already almost twice the industry average (see Tables 2 and 3). Nonetheless, Aspen decided to proceed with the drastic increase of its prices for the Products.

(173) Aspen never carried out any material R&D activity in relation to the Products. Aspen has not in any significant way innovated or improved the Products.

(174) Given that Aspen has outsourced manufacturing to third party manufacturers, Aspen's profits cannot reflect any particular production efficiency of Aspen either.[118]

(175) Regarding distribution, Aspen's activity in relation to the Products has mostly consisted of managing the commercialisation and distribution through external contractors. Also with respect to distribution, Aspen has not introduced material improvements from a customer's perspective. Evidence suggests that, on the contrary, on certain occasions Aspen's price increase strategy may actually have led to supply and distribution problems, such as the so-called "stock-out" situations, where, for instance, a distributor complained [quote from email relating to local supply] due to the stock allocation system Aspen implemented for the Products.[119]

Conclusion

(176) The analysis in the Preliminary Assessment confirmed that Aspen's prices and profits reflect neither any commercial risk-taking activity, nor innovation, investment, or any material improvement regarding the Products undertaken by Aspen. Aspen has provided neither any material benefit from a therapeutic point of view, nor enhanced materially the quality of the Products or their distribution compared with that offered by GSK at the time of the acquisition of the Products. This absence of legitimate reasons suggests an unfairness of the prices, in particular also in view of the nature of the products as old, off-patent medicines and on which patients depend. The Preliminary Assessment therefore reached the preliminary conclusion that there are no

[116] See Aspen's distributors' pricing proposal dated 10 October 2011.
[117] See Recital (14) above.
[118] Aspen has argued that in 2018, Aspen opened a new production facility at Port Elisabeth, South Africa. However, during the Relevant Period […].
[119] See email dated 6 March 2014 where [Aspen's distributor] started complaining to Aspen that [quote from email relating to local supply]. Similarly, by email dated 25 May 2012, [Aspen's distributor] raised concerns to Aspen: [quote from email relating to local supply].

legitimate reasons for Aspen's excessive profits and high prices, raising concerns that Aspen's prices may have been unfair in themselves.

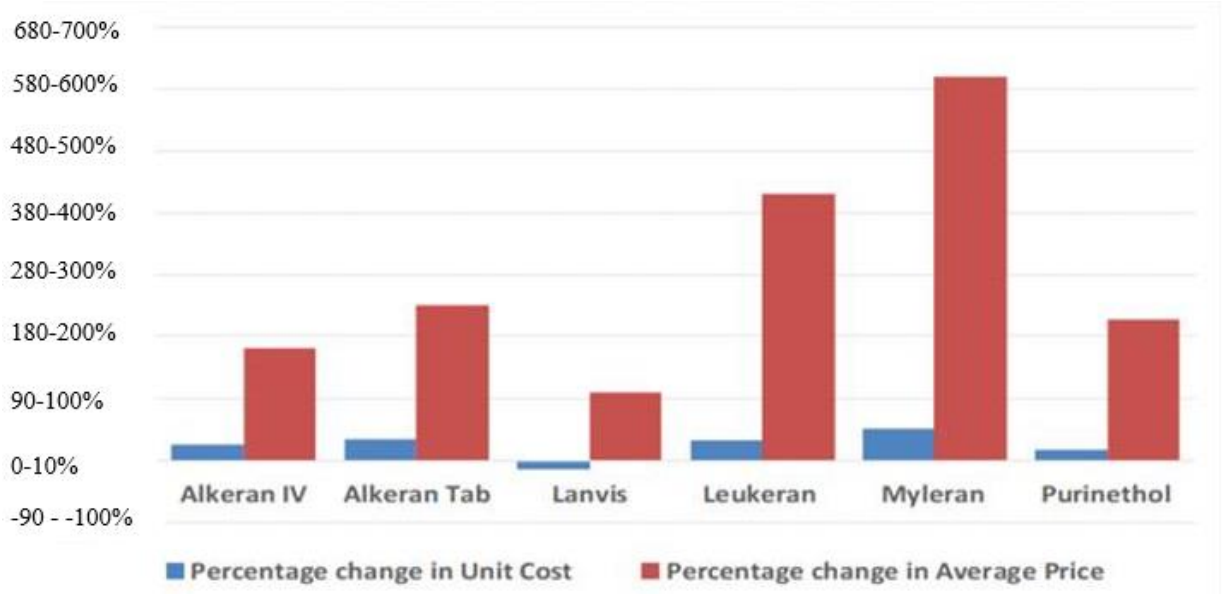
4.6.4.2.2. Disproportionality of the price increases and magnitude of excessive profits

(177) Aspen's price increases of the Products are disproportionate to the increases of its costs during the Relevant Period, where those increases occurred. Moreover, the Commission found in the Preliminary Assessment that Aspen's profits are excessive to a particularly high degree. Both elements supported the Commission's concerns of unfairness.

Aspen's price increases are disproportionate with costs

(178) Aspen's high price increases have been disproportionate[120] to the change of costs of production for the Products (including both direct and indirect costs), as illustrated by Graph 1.

Graph 1: Percentage change in the unit costs of production (EUR / Standard Unit) and the percentage change in average prices, by Product, FY2012 to FY2019, in the EEA (excluding Italy)



Source: Commission's internal analysis based on Aspen accounting data

(179) First, from Graph 1 it is apparent that the high price increases have been disproportionate to the relative increase in costs in the same period for a given Product. For instance, compared with the FY2012 (pre-increase), the costs of production of Alkeran IV, Leukeran and Purinethol increased

[120] Disproportion between a difference in costs and price increases was one element contributing to the Court of Justice's conclusion that a price was unfair and abusive in its Judgment of 11 November 1986 in *British Leyland Public Limited Company v Commission of the European Communities*, 226/86, EU:C:1986:421. In particular, the Court upheld the Commission's Decision of 2 July 1984 in IV/30615 - BL, OJ L 207, 2.8.1984, pp. 11-16. The Court found that the issuance of a certificate of conformity for both left-hand-drive and right-hand-drive vehicles requires *"a simple administrative check which cannot entail significant costs"*. British Leyland ('BL') initially charged *"a single fee for both right-hand-drive and left-hand-drive"* vehicles. For left-hand-drive vehicles (that were converted to right-hand-drive), the certificate would in principle be issued before conversion, and would thereafter be subject to four additional verifications. Although these meant certain additional costs, those verifications could be based on *a "certificate furnished by a garage"* without an *"inspection"* of the vehicle. The cost incurred for a certificate of conformity of a left-hand drive or right-hand-drive vehicle *"cannot therefore justify the charging of different fees"*. However, BL increased *"the fee for* [such] *left-hand-drive vehicles* [to a level that] *was six times greater than that for right-hand-drive vehicles"*. The Court found, therefore, that the fee for left-hand-drive vehicles had been fixed *"not based on costs"* and concluded that *"the fee was [...] clearly disproportionate to the economic value of the service provided"*, suggesting that the Court also considered the charged fees disproportionate to the difference in costs for certificates of conformity for right-hand-drive and left-hand-drive vehicles (see paragraphs 25, 28 and 30).

over the Relevant Period of 7 years by [20-30]%, [30-40]% and [10-20]%, respectively, whereas the prices increased by 180%, 431% and 227%, respectively.[121]

(180) Second, the scale of price increases implemented by Aspen can also not be explained by the fact that certain prices had been loss-making in some Relevant Markets before the price increases. If prices have been loss-making in some Relevant Markets, this allows raising these prices to some extent, but certainly not to a level where the profits and prices become excessive. The Commission also notes that at portfolio level, that is, all Products taken together, the Products were profitable, with an overall EBITDA margin at [40-50]% and therefore significantly higher than the 23% EBITDA margin of the industry (see Tables 2 and 3). Each Product also had a positive EBITDA margin (that is, it was not loss-making) in the EEA in FY2012, with the only exception of Lanvis (which accounted for only [5-10]% of Aspen's sales in FY2012).[122]

(181) In light of the considerations summarised in Recitals (178) to (180), the Preliminary Assessment found that Aspen's price increases for the Products are clearly disproportionate to the change in costs of production. This further supported the Commission's preliminary concerns that Aspen's prices have been unfair.

The magnitude of the excessiveness of Aspen's profits

(182) In the present case, the level of the excessiveness of Aspen's profits is also of such magnitude that it confirms the Commission's preliminary concerns that Aspen's prices were unfair. As explained in Recital (84), in the *Sirena* case, the CJEU held that *"the price level of the product may* [...] *if it is particularly high, be a determining factor"* in showing an abuse.[123] This applies especially, if the price level is particularly high, also when considered in light of costs and profits.

(183) As illustrated in Section 4.6.3, Aspen's prices for each of the Products gave rise to particularly high profits in absolute terms and when compared with the Profitability Comparators during the Relevant Period.

(184) This becomes also very clear when looking at the profit dispersion of the Profitability Comparators:[124] 90% of the profitability observations for the Profitability Comparators are at a profitability level below 37% EBITDA. By comparison, at portfolio level, Aspen earned an EBITDA margin of [80-90]%.[125] Not a single Comparator company in the entire sample of observations achieved such a high margin.

(185) Moreover, as explained in Recital (141) above, the profitability of the Products at portfolio level generated excess profits of [280-300]% above the cost-plus level analysed in Section 4.6.3.3. This illustrates further that Aspen's prices were so high that they resulted in particularly high profits if compared with a likely level of profits and resulting prices in conditions of sufficiently effective competition.

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121 On a per product level, the average increase of Aspen's net prices across the EEA (excluding Italy) lies between [200-220]% and [840-860]% above even the list prices charged by GSK in the years 2004 to 2009 (2009 being the last year GSK sold the Products for its own account).

122 Moreover, despite the fact that in a significant number of Relevant Markets the Products were not loss-making in FY2012, Aspen increased prices in those markets significantly during the period FY2013 to FY2019. This set of Relevant Markets accounted for over [80-90]% of total revenues of the Products taken as portfolio during FY2013 to FY2019. For most of the other Relevant Markets where the Products were loss-making in FY2012 (and where the volume of sales was mostly low), the price increases implemented by Aspen resulted in very high relative and absolute profitability, as shown in the cost-plus analysis.

123 Case C-40/70 Sirena vs Eda Srl and Others (Sirena), paragraph 17. In the same vein, Advocate General Wahl stated in his Opinion of 6 April 2017 in Case C-177/16 *Autortiesību un komunicēšanās konsultāciju aģentūra / Latvijas Autoru apvienība*, paragraph 121, that *"the unfairness of a price can be determined without the need to make any comparison with similar or competing products. The particularly high price in itself reveals the abuse."*

124 The profit dispersion rate describes the range of the distribution, in terms of spread and density, of the value of profit observations of Comparators.

125 Regarding gross margins, 90% of the profitability level observations report a gross margin below 76%, whereas Aspen earned at portfolio level a gross margin of [80-90]%, also not reported by any Profitability Comparator of the sample.

4.6.4.2.3. Aspen's strategy to exploit

(186) The analysis has to consider also the dominant undertaking's conduct and its economic motives. Further, the objective reasons behind Aspen's pricing policy are highly relevant.[126]

(187) According to the Commission's Preliminary Assessment, Aspen's internal documents suggest that having acquired the Products, Aspen became conscious of the market power that it enjoyed, and decided to exploit it (see Section 4.6.2.1). Soon after taking over the management of the Products in 2011, Aspen started to aim for *"a big push to increase the pricing"* in view of a *"Pricing opportunity priority"* (see Recital (87)). It saw this opportunity because "in almost all the markets [...] there is no replacement on the products targeted" .[127]

(188) The Preliminary Assessment found that Aspen took the decision to implement its high price increases without regard to health systems and patients, well aware that it could only do so due to lack of competition.

(189) Aspen's strategy confirms the Commission's preliminary concerns that Aspen imposed its starkly increased prices solely with the aim to use its market power in the absence of effective competition to exploit health systems and patients and to increase its profits.

4.6.4.2.4. Preliminary conclusion on unfairness in itself

(190) The Preliminary Assessment's analysis of unfairness in itself found that Aspen offered no material improvements of the Products and designed and implemented a strategy to exploit health systems and patients. The Commission's preliminary analysis did indeed not reveal any legitimate reasons for Aspen's high prices. Instead, it showed that Aspen's price increases were disproportionate to the limited increases in its costs of production and that Aspen's profit margins were particularly high compared with Profitability Comparators. The Preliminary Assessment did not find any relevant changes of circumstances. On this basis, the Preliminary Assessment found that Aspen's prices for each of the Products in the Relevant Period have been, in themselves, unfair.

4.6.4.2.5. Additional elements confirming the unfairness in itself of Aspen's prices

(191) The Preliminary Assessment considered in its fairness assessment also the particular means and methods that Aspen employed to impose the higher prices and the likely harm those prices may have caused to patients and the national health budgets and concluded that these additional factors confirm the finding of the prices being unfair.

(192) As described in Section 4.6.2, Aspen implemented the price increases with a detailed pan-European strategy designed to overcome legitimate resistance of ministries of health, health systems and pricing and reimbursement authorities. As mentioned in Recital (94), [Aspen external consultant] for instance summarised to local distributors Aspen's instructions for negotiations with national authorities as follows:

> "*Take it or leave it. No other alternative. If the local MOH [Minister of Health] doesn't accept the new price, we will either sell with no reimbursement or not supply at all. No place for negotiations. No time for reference to the other countries.*"[128]

(193) Aspen applied this approach across the EEA. This illustrates the way in which Aspen made the competent national authorities accept the higher price through aggressive means of negotiations, including threats of withdrawal, and relying on the patients' dependency on the Products to overcome resistance against the price increases. Aspen's strategy further included defeating the

[126] See also Advocate General Wahl in his Opinion of 6 April 2017 in Case C-177/16 *Autortiesību un komunicēšanās konsultāciju aģentūra / Latvijas Autoru apvienība*, paragraph 181.

[127] Email dated 1 June 2011 from [Aspen employee] to [Aspen employee] regarding *"Onco Pricing opportunity priority – Europe."*

[128] See Email dated 23 April 2012 from [Aspen external consultant] to [Aspen's distributor] regarding *"the* […] *countries: Pricing and reimbursement COSMOS portfolio."*

purpose of the external reference pricing systems; and a stock-allocation program that risked having an impact on patients' access to the medicines.

(194) Moreover, according to the Preliminary Assessment, Aspen's stark price increases to reach profitability levels many times higher than industry averages had an adverse effect on the total healthcare expenditure in the Member States and at least potentially on their ability to serve patients. As national health systems were forced to pay more to Aspen, the corresponding amounts may well have not been available for other health needs, considering that health budgets are finite. The United Kingdom National Health Service, for example, explained this concern to the Commission as follows:

> "*The NHS has a limited pot of money, so the more it spends on the drugs bill, the less it can afford other healthcare services, for example we have estimated that an increase of £4.3 million to the drugs bill [caused by Aspen's products per annum] means a loss of 332 Quality Adjusted Life Years (QALYs), which is the standard unit of health (this would include 22 additional patient deaths which otherwise would have been avoided). However, we cannot specifically allocate this to Aspen, because there are other cost pressures apart from de-branding*."[129]

(195) Both the means of implementing and imposing the price increases and the potential harm to patients and health systems further confirmed the preliminary conclusion of unfairness of Aspen's prices, although that conclusion is not a necessary condition for finding concerns under Article 102(a) TFEU.

4.6.4.3. Unsuitability of potentially available comparators

(196) The Preliminary Assessment already established the unfairness of Aspen's prices "in itself" under the first alternative of the test in Limb 2. There was therefore no need to consider the second alternative under Limb 2 (comparison with competing products).

(197) Nonetheless, the Preliminary Assessment also considered the potential suitability of some other products for assessing unfairness to reply to Aspen's arguments in this respect. It reached the preliminary conclusion that potential generic and innovative price comparator products put forward by Aspen do not challenge the preliminary finding that Aspen's prices are in themselves unfair.

(198) First, as concerns potential comparators in form of generic versions of any of the Products, only two different products of two generic suppliers, each for one of the Products, have been present on two national markets since long before Aspen acquired the Products from GSK: Vis has been present with Mercaptopurine Vis in Poland since 1979,[130] and Techni-Pharma with Techni-Pharma Chlorambucil in France since 1956 (where Aspen has not been selling). Both products, respectively, have been selling at very low prices compared with Aspen's Purinethol and Leukeran prices. The very low price level of both Mercaptopurine Vis and Techni-Pharma Chlorambucil, if anything, suggests that Aspen's prices for Purinethol and Leukeran are unfair.

(199) As concerns recent generic entrants in some markets, most generic suppliers have entered Relevant Markets with prices broadly aligned with Aspen's price levels, and their prices have remained broadly aligned with Aspen's prices. Regarding those price levels of generic suppliers, the Commission has serious doubts that they reflect levels of sufficiently effective competition. In fact, empirical data suggests that sufficiently effective generic price competition may require more than one or two entrants, which is not the case on any of the Relevant Markets. The empirical data also suggests that small market sizes may delay the emergence of effective generic competition, and

[129] See reply to Commission RFI of 24 July 2017 provided by the United Kingdom Department of Health.
[130] According to Aspen, Vis has also had some sales in Latvia more recently.

that it may take a significant amount of time in small markets for prices to drop to levels likely reflecting effective competition.[131] Moreover, in the present case, as set out in the Preliminary Assessment, the Commission has concrete indications in relation to the profit levels of some generic entrants that suggest that the Relevant Markets (where entry has occurred) have not yet entered into a phase of effective generic price competition. For those reasons, the Commission preliminarily concluded that prices of recent generic entrants in the Relevant Markets are not suitable comparators for assessing the unfairness of Aspen's price levels.

(200) Second, innovative products, unlike Aspen's Products, benefit from various forms of legal exclusivity granted by the legislator to reward risk-taking, investment and innovation. In recognition of those efforts, pricing and reimbursement negotiations for innovative products follow different rules compared with off-patent products. This applies also to a novel formulation benefitting from orphan market exclusivity. For this reason, exclusivity protected products[132] could not provide any meaningful insights into price levels that would have reflected sufficiently effective competition for off-patent drugs, making them generally unsuitable as comparators for off-patent medicines, such as the Products.

4.6.4.4. Preliminary conclusion on Limb 2

(201) Based on Recitals (161) to (200), the Preliminary Assessment reached the preliminary conclusion that Aspen's prices for each of the Products during the Relevant Period may have been unfair.

4.6.5 No objective justification

(202) Conduct meeting the conditions of excessiveness and unfairness can escape the characterisation as an abuse pursuant to Article 102 TFEU, if the dominant undertaking demonstrates an objective justification to the required legal standard of proof.[133]

(203) As explained above in Section 4.6.3.3.3, Aspen argued that the imposed price levels for the Products were necessary to secure a sufficient return on its investment in the Products, in light of the acquisition price paid by Aspen to GSK. The Preliminary Assessment found that a possible need for Aspen to recoup its investment in the Products could not justify the price levels Aspen has charged (see Recital (158)).

(204) In addition, Aspen suggested that price increases were driven by (i) the need to recoup increases in the conversion costs (being the costs of procuring finished fully-packed products from third party manufacturers) and in the costs of API in the period following the acquisition of the Products from GSK in a manner that Aspen had not anticipated, or by (ii) the need to cross-subsidise certain markets where the Products were loss-making. However, for the reasons already explained in Sections 4.6.3.3 and 4.6.4.2.2 above, the Preliminary Assessment found that none of these explanations can legitimise the level of the price increases and the level of the prices Aspen imposed. In particular, as shown in Graph 1 in Section 4.6.4.2.2 above, the change in costs of production cannot explain objectively the magnitude of the price increases for each of the Products. Similarly, as explained in Recital (180) above, cross-subsidisation between markets cannot give a dominant undertaking carte blanche to disproportionately hike up prices, especially in a context, such as that at stake, where the Products were profitable at portfolio level already before the price increases (see Table 4 above).

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131 See in particular the European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, Annexes to Chapter B – Part II of the Report, pp. 556-598. Similarly, a study from the U.S. suggests that up to six or seven generics entrants may be required to compete down high prices, see https://www.fda. gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices.

132 One such exclusivity protected product is for example a new mercaptopurine medicine (Xaluprine), different from Aspen's Purinethol (mercaptopurine), which has been brought to the market with a novel, oral suspension formulation of mercaptopurine, used in particular for paediatric treatments. While that novel medicine was considered to be part of the relevant product market, it is not suitable as price comparator.

133 See Recital (5) of Regulation 1/2003.

(205) Finally, Aspen argued that the Products presented all the characteristics of orphan drugs. Only, the Products would not have benefited from this designation as the 1999 Orphan Drug Regulation was not yet in place at the time the Products were first developed and marketed in the EEA. According to Aspen, given the orphan and specialty nature of the Products, the profitability of the Products would need to be higher. However, the Preliminary Assessment found that the Products had already been on the market for decades before the Orphan Drug Regulation entered into force some 20 years ago and would not fulfil the criteria for obtaining an orphan designation. It is clear, therefore, that in the present case the Orphan Drug Regulation cannot justify the level of the prices.

(206) Aspen did not submit any other grounds to justify its pricing conduct. In light of the above, the Commission has reached the preliminary conclusion that there is no objective justification for Aspen's conduct. Based on this, the Preliminary Assessment concluded that there is no objective justification for Aspen's conduct.

4.6.6 Substantial part of the internal market and effect on trade between Member States

(207) The Preliminary Assessment revealed that Aspen's conduct has taken place in numerous EEA Member States and, therefore, that the alleged abuse of a dominant position has taken place in a substantial part of the internal market. Moreover, as the supply of Aspen's product involved trade in the entire territory of Member States and trade across Member States, the Preliminary Assessment concluded that Aspen's conduct may have been capable of appreciably affecting trade between Member States.

4.7. Conclusion of the Preliminary Assessment

(208) In view of the considerations summarised in Sections 4.3 to 4.6, the Preliminary Assessment concluded that, through its conduct, Aspen (i) may have been earning excessive profits in most of the Relevant Markets during the Relevant Period, and may continue to do so, and (ii) charged prices that for each of the Products in most of the Relevant Markets during the Relevant Period may have been, and may continue to be, unfair in themselves. There was also no objective justification for such prices. Accordingly, the Commission's preliminary conclusion was that Aspen's prices may not have had, and continue not to have, any reasonable relation to the economic value of the Products supplied. The Relevant Markets concerned cover the overwhelming majority of the overall revenues from the Products. Therefore, the Commission's preliminary concerns have been that Aspen's behaviour may amount to an abuse of a dominant position, through the application of unfair (excessive) prices, in breach of Article 102(a) TFEU and Article 54(a) of the EEA Agreement.

5. PROPOSED COMMITMENTS

(209) On 9 July 2020, Aspen submitted the Proposed Commitments with two key elements, a price commitment[134] and a supply commitment[135]:

5.1. Price commitment and Transitory Rebate

(210) Aspen would commit to reduce its net prices for each of the Products in all of the EEA Member States where price levels might raise concerns and would take the necessary steps towards Regulatory Authorities[136] to implement these reductions as quickly as possible. The reduced net prices of the Products ("Reduced Net Prices") would be set out per Member State and per Product. The price reduction would be on average around 73% for the Products across the EEA. After the reduction by Aspen, there would still remain a significant variation in the prices between Member States, because Aspen's per-unit costs would differ between the Member States. The committed

[134] See paragraphs 6-15 of the Proposed Commitments and the Final Commitments.
[135] See paragraphs 16-19 of the Proposed Commitments and the Final Commitments.
[136] As defined in paragraph 5 of the Proposed Commitments and the Final Commitments. A list of Regulatory Authorities is listed in Annex 4 of the Proposed Commitments.

net prices would be maximum net prices, namely price-ceilings, and Aspen would be free to apply lower prices.

(211) The Reduced Net Prices would apply for a period of 10 years from the day of notification of the Commission's Decision accepting the Proposed Commitments. In the second half of the period, namely after year five, there could be a one-off review of the committed price levels in case of a significant increase in Aspen's direct costs. In addition, Aspen would commit to apply the Reduced Net Prices retroactively from 1 October 2019, the date when Aspen first approached the Commission with a concrete commitments proposal. Aspen would reimburse the amounts paid in excess of the Reduced Net Prices during the period from 1 October 2019 until the moment that Aspen has effectively implemented the price reductions (Transitory Rebate[137]) to public and private entities that ultimately pay or reimburse medicine prices in the Member States (Appropriate Beneficiaries[138]), as set out in the Proposed Commitments. Those payments would be without prejudice to any claims under applicable civil or commercial laws.

5.2. Supply commitment

(212) Aspen would commit to continue supplying the Products for a guaranteed period of 5 years as of notification of this Decision. For a second subsequent five-year period, Aspen would continue supplying the Products unless Aspen intends to discontinue supplying, in which case, Aspen commits to (i) inform, at least one year in advance, the Member State authorities concerned of that intention, and (ii) make the Products' marketing authorisations available to any interested third party and to maintain the marketing authorisations until it has found a purchaser.

6. COMMISSION NOTICE PURSUANT TO ARTICLE 27(4) OF REGULATION 1/2003

(213) The Commission published the Article 27(4) notice on 15 July 2020. In response, the Commission received 30 submissions from interested third parties, which included primarily national pricing and reimbursement authorities, but also consumer organisations, cancer organisations and patient organisations at European and national level.

(214) The respondents welcomed the Proposed Commitments as an effective contribution to ensuring that the Products will be affordable and accessible.

6.1. Respondents' view on the commitments

6.1.1 Reduced Net Prices

(215) The replies to the market test, in particular, welcomed the average 73% price reduction in the EEA leading to individual price ceilings for net prices that Aspen may charge per Product in each Member State concerned for a period of 10 years.

(216) Regarding the Reduced Net Prices that would be applied in each Member State concerned as set out in Table 1 of the Proposed Commitments, some respondents suggested that, for a limited number of Products in some Member States, additional Reduced Net Prices should be added. That additional reduction concerned Products (or different pack sizes of the Products) which Aspen did not sell during FY2019, being the reference period on which the prices for the Products included in Table 1 are based. Since then, Aspen has started, or is planning to sell the Products in some Member States where it previously did not sell them before. For such Products (or pack sizes), respondents requested to complete Table 1 with additional Reduced Net Prices.

6.1.2 Transitory Rebate

[137] As defined in paragraph 9 of the Proposed Commitments and the Final Commitments.

[138] As defined in paragraph 5 of the Proposed Commitments and the Final Commitments. A list of Appropriate Beneficiaries is listed in Annex 1 of the Proposed Commitments.

(217) The Transitory Rebate is a mechanism of the Proposed Commitments designed to ensure that Aspen charges no higher prices than the Reduced Net Prices from the date on which the Reduced Net Prices take effect (1 October 2019) to the date that the list prices of the Products will have been effectively reduced. This means that Aspen would have to pay, for this period, the difference between Aspen's actual net sales and its hypothetical net sales had those same quantities been sold at the Reduced Net Prices.

(218) The Transitory Rebate has a prospective and a retroactive component. It applies prospectively for the period from the date of notification of this Decision until the medicines' list prices are effectively reduced or, where list prices do not form part of the national system, until Aspen's Reduced Net Prices become otherwise effective. It applies retroactively from 1 October 2019 until the date of notification of this Decision. The Transitory Rebate would ensure that during the transitional period ultimately Aspen charges no excessive prices to health system or patients. For the two Member States concerned, Czechia and Germany, where – to some limited extent – co-payment by patients existed, the Proposed Commitments foresee that patients who paid a certain part of the medicine price themselves would receive from Aspen the corresponding part of the Transitory Rebate.

(219) Some respondents asked Aspen to simulate a Transitory Rebate calculation for their Member State to understand how much Aspen overcharged and to understand the potential amount of the Transitory Rebate that an Appropriate Beneficiary could expect. Those calculations have shown that Transitory Rebate amounts will not be identical with any higher reimbursement amounts made by health systems as a direct or indirect result of the pricing practice. Those amounts are in fact by definition not the same, *inter alia* because of differences between manufacturer sales prices and reimbursement amounts, given that reimbursement amounts are based on prices that include the profit margins at the different levels of the distribution chain and because of possible volume differences resulting from the time lag between the manufacturer sale into a country, the actual use and later reimbursement.

(220) Other respondents queried whether the Transitory Rebate covered Products reimbursed by national reimbursement authorities that had been purchased from parallel traders or those that had been purchased from Aspen in another country, namely imported by national reimbursement authorities through a special licence (so-called Foreign Packs[139]).

(221) In the two Member States where "co-payment" exists, some respondents were interested in understanding more precisely the methodology in Aspen's Proposed Commitments for calculating the "co-payment" amount of the Transitory Rebate. One respondent pointed out that the Proposed Commitments were not clear enough with regard to the date and available time for patients to submit their claims to Aspen.

(222) Some respondents suggested adjustments to the Proposed Commitments regarding the identities of the Appropriate Beneficiaries, of the residual fall back recipient that would receive any remaining amount that Aspen failed to distribute (Annex 1 and Table 1 of the Proposed Commitments[140]) and of the Regulatory Authorities in Annex 4 to the Proposed Commitments.

(223) Finally, some respondents mentioned that the retroactive application of the Transitory Rebate should be extended for the entire duration of the Relevant Period, as a form of compensation for the harm suffered by national health systems and patients in the past.

6.1.3 Supply commitment

[139] See also definition in paragraph 5 of the Final Commitments.

[140] The Final Commitments use the word 'Appendix' instead of 'Annex', and Table A (of Appendix 1) instead of Table 1.

(224) The replies to the market test welcomed Aspen's commitment to supply the Products for a guaranteed minimum period of 5 years as well as the commitment, for a second five year period, for Aspen to continue supply or, should Aspen decide to discontinue commercialising a Product in a Member State, to (i) give 12 months' notice to national authorities; and (ii) make the Products' marketing authorisations available for sale to an interested third party.

(225) One respondent suggested increasing the notice period from 12 months to at least 18 months to provide national authorities with sufficient time in view of certain national regulatory restrictions.

6.2. The Final Commitments

(226) Aspen has made modifications to its Proposed Commitments to address the comments received in response to the Article 27(4) notice, and submitted revised commitments on 28 January 2021. The main modifications are summarised in Recitals (227) to (234).

6.2.1 Additional Reduced Net Prices

(227) Taking into account the market test comments and new sales developments, Aspen has completed Table 1 of the Proposed Commitments with Reduced Net Prices for medicines or pack sizes which Aspen did not sell during its FY2019 in certain Member States, but which it has started, or is planning, to sell in those Member States since the end of its FY2019.

(228) The Member States concerned for which Aspen included in Table 1 of the Proposed Commitments Reduced Net Prices for additional medicines and pack sizes are the following: Estonia (Alkeran IV), Hungary (Leukeran 25, Alkeran IV), Iceland (Leukeran 25), Lithuania (Alkeran tablet 25, Lanvis 25), Romania (Myleran 100), Slovakia (Myleran 100) and Spain (Alkeran tablet 25, Alkeran IV, Lanvis 25).

6.2.2 Transitory Rebate

(229) Aspen has clarified with respect to sales by parallel traders to other Member States that Aspen will calculate the Transitory Rebate based on where Aspen placed the Products on the market for the first time. The destination country to which parallel traders made their sales is not relevant, even if the parallel-traded products may have been reimbursed there. This corresponds to the principal objective and the purpose of the Proposed and the Final Commitments, which is to ensure that Aspen no longer sells at excessive prices. As a consequence, for the destination country of the parallel import (where it was not Aspen selling the product), the Transitory Rebate excludes purchases from parallel traders (as per paragraph 9 of the Final Commitments), whereas the parallel-export country includes Aspen's sales (even if they may have subsequently been exported by parallel traders).

(230) In contrast, Aspen's Foreign Packs sales are accounted for in the country of destination, because Aspen, or Aspen's Agents, sell the Products through Foreign Packs directly to the importing country and negotiate the price with the importing country. Aspen has clarified this in the Final Commitments.[141]

(231) For Czechia, where co-payment rules apply with respect to the Products, Aspen has adapted its notification mechanism for patients, reflecting the position of the health insurance funds.

(232) Aspen has updated the Transitory Rebate mechanism for a limited number of Member States to take account of the market test comments. Furthermore, also reacting to comments from the market test, Aspen has updated the lists of Appropriate Beneficiaries contained in Appendix 1 (including Table A) of the Final Commitments, the name of the residual fall back recipient contained in Appendix 1 and of Regulatory Authorities contained in Appendix 4 of the Final Commitments.

[141] See paragraph 5 ('Foreign Pack Sales') and paragraph 9 of the Final Commitments.

(233) Finally, with respect to the comments suggesting a retroactive application of the Transitory Rebate for the entire Relevant Period, it should be noted that commitments in the context of Article 9 of Regulation 1/2003 have the purpose of addressing the preliminary competition concerns as set out in the Commission's Preliminary Assessment and not of compensating all those who may have suffered harm through the suspected infringement. This Decision and the Final Commitments therefore provide primarily a prospective remedy to the excessive pricing concerns in the form of Reduced Net Prices and a supply commitment, rather than a compensation mechanism for the past. The early entry into effect of the Reduced Net Prices as of 1 October 2019 is due to the fact that on this date Aspen first approached the Commission with a concrete commitments proposal and offered to retain, in the Proposed and the Final Commitments, this date for the Reduced Net Prices to take effect. However, the Decision is without prejudice to any claims under applicable civil or commercial laws.

6.2.3 Supply commitment

(234) Aspen has increased the notice period from 12 to 18 months for notifying Regulatory Authorities in the case where Aspen intends to discontinue commercialising any relevant Product after the initial 5-year supply commitment period. This change accommodates the comments received during the market test where some Member States requested more time to prepare for alternative products in the event of discontinuation of commercialisation of a relevant Product.

7. ASSESSMENT OF THE FINAL COMMITMENTS

7.1. Principles

(235) In the context of Article 9 of Regulation 1/2003, the Commission must ensure, firstly, that the commitments in question effectively address the concerns expressed by the Commission in its Preliminary Assessment (effectiveness assessment) and, secondly, that the undertaking concerned has not offered less onerous commitments that would also address those concerns adequately (proportionality assessment). When carrying out that assessment, the Commission must take into consideration the interests of third parties.[142]

7.2. Effectiveness and proportionality of the Final Commitments

(236) The Final Commitments offered by Aspen effectively address the concerns identified by the Commission in its Preliminary Assessment.

7.2.1 The reduced prices remove concerns of excessiveness and unfairness of Aspen's price levels

(237) The Final Commitments reduce Aspen's prices for the Products to levels that can no longer be considered abusive within the meaning of Article 102(a) TFEU and Article 54(a) of the EEA Agreement.

(238) The Commission has carefully assessed Aspen's Reduced Net Prices set out in the Final Commitments, and considers that Aspen's very significant price reductions remove the excessiveness of its profit margins within the meaning of Limb 1 of the *United Brands* judgment in all Relevant Markets and also the unfairness of its prices within the meaning of Limb 2 of the *United Brands* judgment.

(239) Following the price reductions, Aspen's prices will exceed the cost-plus level described in the Limb 1 assessment (see Section 4.6.3.3.2) by [10-20]% on average across the Relevant Markets[143]. As explained in Recitals (132) to (138), exceeding to some degree the cost-plus level does not automatically lead to concerns of excessive pricing. The cost-plus-level as such represents only a

[142] Judgment of the Court of Justice of 29 June 2010, *Commission v Alrosa*, Case C-441/07 P, EU:C:2010:377, paragraph 41 and Judgment of the Court of Justice of 9 December 2021, *Groupe Canal + SA*, C-132/19 P, EU:C:2020:1007, paragraphs 105-106.

[143] At a level of the various Relevant Markets, the respective excess over the cost-plus level does not exceed this average by more than [0-5] percentage points.

proxy-benchmark that is based (i) on (a case-specific) average profitability of comparable undertakings in the sector (the "plus"), and that is (ii) added to Aspen's costs. Many companies have prices and earn profit margins that exceed to some extent the *average* profitability in a sector, while other companies have prices and margins below the mathematical average in the sector. Not every upward deviation from the average can automatically lead to excessiveness within the meaning of Limb 1. Therefore, and as explained further in Recitals (132) to (138), only prices that exceed the cost-plus level *significantly* may amount to an exploitative abuse and the assessment must be made in view of the specific circumstances of each case.

(240) Under the Final Commitments, Aspen will charge prices earning profit margins dropping to a level that no longer raises concerns of excessiveness. Aspen's profit margins, whether on a portfolio or Relevant Market level, will remain within the range of profit margins commonly observed in the sector by comparable undertakings, as shown by the Commission's Profitability Comparator analysis. In this analysis, the Commission considered the concrete dispersion and variance of profit margins of the Profitability Comparators, as well as the relevant circumstances in relation to the products and the markets concerned.

(241) In addition, the Commission took into consideration that Aspen's sales volumes have been showing a downward trend, and that, as a consequence, Aspen's per unit costs in the future are likely to increase rather than to decrease, while the Final Commitments provide for a fixed price ceiling over a ten-year period, with only one possibility of review under limited circumstances.

(242) The Commission therefore considers that Aspen's reduced price and profit levels no longer raise concerns of excessiveness within the meaning of Limb 1 of the *United Brands* judgment.

(243) Moreover, Aspen's Reduced Net Prices will bring the average price of the Products below the level when the price increases started. The Commission notes that, under the Final Commitments, Aspen will, on a portfolio level, more than reverse the price increases it implemented from mid-2012, bringing the average prices of the Products significantly below the pre-increase price levels (that is the levels in place when Aspen took over the management of the Products from GSK). In relation to the markets where Aspen had charged prices which led to earning high profits already before increasing its prices, Aspen will reduce its prices to a particularly substantial degree below the pre-increase price levels, thus removing the unfairness of its prices and reducing its profit margins to a level that no longer raises concerns.

(244) The Commission therefore considers that Aspen's reduced price and profit levels no longer raise concerns of unfairness within the meaning of Limb 2 of the *United Brands* judgment.

(245) The fact that Aspen's Final Commitments more than reverse the price increases that Aspen implemented is an additional element that contributes to removing the Commission's preliminary concerns under Article 102(a) TFEU and Article 54(a) of the EEA Agreement.

7.2.2 The ten year period of Aspen's price commitments and the Transitory Rebate period starting on 1 October 2019

(246) Aspen's Reduced Net Prices will apply for a period of 10 years, with one possible review after 5 years only, and retroactively from 1 October 2019 onwards by way of a Transitory Rebate.

(247) The Commission considers the ten-year period (in addition to the period starting from 1 October 2019) to be proportionate and at the same time sufficiently long to address the Commission's concerns, while also providing certainty to market participants for a sufficiently long period. The possibility of a review of Aspen's prices after 5 years contributes to the Commission's finding of proportionality, given that during a 10 years period market conditions or costs may fluctuate materially, possibly justifying an adjustment of the Reduced Net Prices.

7.2.3 Aspen's supply commitment

(248) Aspen commits to continue supplying the Products for a guaranteed first period of 5 years. For a second five-year period, Aspen commits to continue supplying or, if Aspen intends to discontinue supplying any of the Products in any market, to inform the authorities of the Relevant Countries 18 months in advance while making the Products' marketing authorisations available to any interested third party (and maintaining the marketing authorisations until it has found a third party purchaser).

(249) The Commission considers that the initial five-year supply commitment, supplemented by an additional five-year commitment either to supply the Products or to make the marketing authorisations available to an interested third party, is proportionate and at the same time sufficiently long to protect the interests of third parties, in particular health systems and patients. Aspen's supply commitment enhances the effectiveness of the price commitments. Aspen's obligation to alert authorities 18 months before implementing any possible plans to discontinue supplying any of the Products is sufficient to safeguard third parties' interests by facilitating the continuation of supply by an alternative supplier and/or by giving the time to health authorities to respond appropriately in order to avoid shortages of supply.

7.2.4 Effective monitoring of Aspen's implementation of the Final Commitments

(250) Aspen's implementation of the Final Commitments will be subject to ongoing independent expert review by a Monitoring Trustee, acting under the Commission's supervision, for the entire duration of the Final Commitments. The use of a Monitoring Trustee, the appointment process and the powers of the Monitoring Trustee are standard practice in such cases.

7.2.5 Conclusion on effectiveness and proportionality

(251) The Commission considers that Aspen's Final Commitments effectively remove the Commission's concerns identified in its Preliminary Assessment.

(252) Aspen has not offered less onerous commitments in response to the Preliminary Assessment that would also address the Commission's concerns adequately. No third party has given any indication that the Proposed Commitments would affects its contractual rights, let alone empty them of their substance.

(253) The Commission has taken into consideration the interests of third parties, including those of the interested third parties that have responded to the Article 27(4) notice.

(254) The Final Commitments and this Decision declaring them binding, therefore, comply with the principle of proportionality.

8. CONCLUSION

(255) By adopting a decision pursuant to Article 9(1) of Regulation 1/2003, the Commission makes commitments, offered by the undertaking concerned to meet the Commission's concerns expressed in its Preliminary Assessment, binding upon it. Recital (13) of Regulation 1/2003 states that such a decision should not conclude whether or not there has been or still is an infringement.

(256) The Commission's assessment of whether the Final Commitments offered are sufficient to meet its concerns is based on its Preliminary Assessment, representing the preliminary view of the Commission supported by the underlying investigation and analysis and the observations received from third parties following the publication of a notice pursuant to Article 27(4) of Regulation 1/2003.

(257) As far as the United Kingdom is concerned, in light of Article 92(1) of the EU-UK Withdrawal Agreement, this Decision declares the Final Commitments binding on Aspen insofar as they relate to the United Kingdom for the period until 31 December 2020. This concerns, in particular, the effective application of the Reduced Net Prices as of 1 October 2019 until that time. As regards the

period following 1 January 2021, this Decision takes note that Aspen's Final Commitments in Annex 3 include the United Kingdom.

(258) In the light of the Final Commitments offered, the Commission considers that there are no longer grounds for action on its part as regards the concerns set out in the Preliminary Assessment and, without prejudice to Article 9(2) of Regulation 1/2003, the proceedings in this case should therefore be brought to an end.

(259) The Commission retains full discretion to investigate and open proceedings under Article 102 TFEU and Article 54 of the EEA Agreement as regards practices that are not the subject matter of this Decision.

HAS ADOPTED THIS DECISION:

Article 1

The Final Commitments in Annex 3 to this Decision shall be binding on Aspen Pharmacare Holdings Ltd and ASPEN PHARMA IRELAND LIMITED for the European Union and the European Economic Area. With respect to the United Kingdom, the Final Commitments in Annex 3 shall be binding on Aspen Pharmacare Holdings Ltd and ASPEN PHARMA IRELAND LIMITED insofar as they relate to the period until 31 December 2020, and the Commission takes note of them insofar as they relate to the period starting on 1 January 2021.

Article 2

This Decision shall apply for a period of 10 years from the date of the notification of this Decision to Aspen Pharmacare Holdings Ltd and ASPEN PHARMA IRELAND LIMITED .

Article 3

There are no longer grounds for action by the Commission in this case.

Article 4

This Decision is addressed to:

Aspen Pharmacare Holdings Ltd
Aspen Place, 9 Rydall Vale Park
Douglas Saunders Drive, La Lucia Ridge Office Park
Durban, Kwa-Zulu Natal, 4051
P.O. Box: 25125, Gateway, KwaZulu Natal, 4321
South Africa

ASPEN PHARMA IRELAND LIMITED
One George's Quay Plaza
Dublin 2
Ireland

Done at Brussels, 10.2.2021

For the Commission
Margrethe VESTAGER
Executive Vice-President

Annex Table 1: Profitability Analysis for Alkeran (Injection)

	2012						2013-2019					
Country	**Volumes ('000 SU)**	**Net Sales ('000 €)**	**Avg. Price (€/SU)**	**Avg. Cost (€/SU)**	**% EBITDA Margins**	**% Excess over "Cost Plus"***	**Volumes ('000 SU)**	**Net Sales ('000 €)**	**Avg. Price (€/SU)**	**Avg. Cost (€/SU)**	**% EBITDA Margins**	**% Excess over "Cost Plus"***
Austria	[…]	[…]	[…]	[…]	[70-80] %	[260-280]%	[…]	[…]	[…]	[…]	[80-90]%	[400-420]%
Belgium	[…]	[…]	[…]	[…]	-[100-120]%	-[60-70]%	[…]	[…]	[…]	[…]	[70-80]%	[260-280]%
Bulgaria												
Croatia												
Cyprus												
Czech Rep.	[…]	[…]	[…]	[…]	-[10-20]%	-[30-40]%	[…]	[…]	[…]	[…]	[80-90]%	[360-380]%
Denmark	[…]	[…]	[…]	[…]	[60-70]%	[140-160]%	[…]	[…]	[…]	[…]	[80-90]%	[500-520]%
Estonia	[…]	[…]	[…]	[…]	-[100-120]%	-[60-70]%	[…]	[…]	[…]	[…]	[60-70]%	[120-140]%
Finland	[…]	[…]	[…]	[…]	[50-60]%	[50-60]%	[…]	[…]	[…]	[…]	[80-90]%	[440-460]%
France	[…]	[…]	[…]	[…]	[50-60]%	[80-90]%	[…]	[…]	[…]	[…]	[60-70]%	[120-140]%
Germany	[…]	[…]	[…]	[…]	[70-80]%	[160-180]%	[…]	[…]	[…]	[…]	[80-90]%	[360-380]%
Greece	[…]	[…]	[…]	[…]	[10-20]%	-[10-20]%	[…]	[…]	[…]	[…]	[80-90]%	[320-340]%
Hungary												
Iceland	[…]	[…]	[…]	[…]	[70-80]%	[240-260]%	[…]	[…]	[…]	[…]	[80-90]%	[380-400]%
Ireland	[…]	[…]	[…]	[…]	[60-70]%	[100-120]%	[…]	[…]	[…]	[…]	[80-90]%	[400-420]%
Latvia												
Lithuania	[…]	[…]	[…]	[…]	[60-70]%	[90-100]%	[…]	[…]	[…]	[…]	[80-90]%	[460-480]%
Malta												
Netherlands	[…]	[…]	[…]	[…]	[30-40]%	[20-30]%	[…]	[…]	[…]	[…]	[70-80]%	[260-280]%
Norway							[…]	[…]	[…]	[…]	[80-90]%	[600-620]%
Poland	[…]	[…]	[…]	[…]	[50-60]%	[70-80]%	[…]	[…]	[…]	[…]	-[30-40]%	-[40-50]%
Portugal	[…]	[…]	[…]	[…]	[40-50]%	[30-40]%	[…]	[…]	[…]	[…]	[80-90]%	[400-420]%
Romania							[…]	[…]	[…]	[…]	[70-80]%	[200-220]%
Slovakia	[…]	[…]	[…]	[…]	-[20-30]%	-[30-40]%	[…]	[…]	[…]	[…]	[80-90]%	[340-360]%
Slovenia		[…]					[…]	[…]	[…]	[…]	[80-90]%	[300-320]%
Spain							[…]	[…]	[…]	[…]	[40-50]%	[40-50]%
Sweden	[…]	[…]	[…]	[…]	[30-40]%	[20-30]%	[…]	[…]	[…]	[…]	[80-90]%	[420-440]%
U.K.	[…]	[…]	[…]	[…]	[40-50]%	[40-50]%	[…]	[…]	[…]	[…]	[80-90]%	[400-420]%
All	[…]	[…]	[…]	[…]	**[50-60]%**	**[80-90]%**	[…]	[…]	[…]	[…]	**[80-90]%**	**[300-320]%**

* Based on benchmark margin of 23% (EBITDA benchmark)

Annex Table 2: Profitability Analysis for Alkeran (Tablets)

	2012						2013-2019					
Country	**Volumes ('000 SU)**	**Net Sales ('000 €)**	**Avg. Price (€/SU)**	**Avg. Cost (€/SU)**	**% EBITDA Margins**	**% Excess over "Cost Plus"***	**Volumes ('000 SU)**	**Net Sales ('000 €)**	**Avg. Price (€/SU)**	**Avg. Cost (€/SU)**	**% EBITDA Margins**	**% Excess over "Cost Plus"***
Austria	[…]	[…]	[…]	[…]	-[10-20]%	-[30-40]%	[…]	[…]	[…]	[…]	[60-70]%	[120-140]%
Belgium	[…]	[…]	[…]	[…]	-[700-720]%	-[90-100]%	[…]	[…]	[…]	[…]	[40-50]%	[40-50]%
Bulgaria												
Croatia												
Cyprus	[…]	[…]	[…]	[…]	-[220-240]%	-[70-80]%	[…]	[…]	[…]	[…]	-[220-240]%	-[70-80]%
Czech Rep.	[…]	[…]	[…]	[…]	-[160-180]%	-[70-80]%	[…]	[…]	[…]	[…]	[40-50]%	[30-40]%
Denmark	[…]	[…]	[…]	[…]	-[70-80]%	-[50-60]%	[…]	[…]	[…]	[…]	[60-70]%	[140-160]%
Estonia	[…]	[…]	[…]	[…]	-[70-80]%	-[50-60]%	[…]	[…]	[…]	[…]	[5-10]%	-[10-20]%
Finland	[…]	[…]	[…]	[…]	-[50-60]%	-[50-60]%	[…]	[…]	[…]	[…]	[60-70]%	[100-120]%
France	[…]	[…]	[…]	[…]	-[70-80]%	-[50-60]%	[…]	[…]	[…]	[…]	[70-80]%	[240-260]%
Germany	[…]	[…]	[…]	[…]	[50-60]%	[60-70]%	[…]	[…]	[…]	[…]	[70-80]%	[200-220]%
Greece							[…]	[…]	[…]	[…]	[80-90]%	[320-340]%
Hungary	[…]	[…]	[…]	[…]	-[70-80]%	-[50-60]%	[…]	[…]	[…]	[…]	[50-60]%	[60-70]%
Iceland							[…]	[…]	[…]	[…]	-[90-100]%	-[60-70]%
Ireland	[…]	[…]	[…]	[…]	[0-5]%	-[20-30]%	[…]	[…]	[…]	[…]	[50-60]%	[70-80]%
Latvia	[…]	[…]	[…]	[…]	-[60-70]%	-[50-60]%	[…]	[…]	[…]	[…]	-[10-20]%	-[30-40]%
Lithuania	[…]	[…]	[…]	[…]	-[70-80]%	-[50-60]%	[…]	[…]	[…]	[…]	[50-60]%	[60-70]%
Malta												
Netherlands	[…]	[…]	[…]	[…]	[20-30]%	[0-5]%	[…]	[…]	[…]	[…]	[70-80]%	[220-240]%
Norway	[…]	[…]	[…]	[…]	[20-30]%	[0-5]%	[…]	[…]	[…]	[…]	[70-80]%	[180-200]%
Poland	[…]	[…]	[…]	[…]	[70-80]%	[160-180]%	[…]	[…]	[…]	[…]	[70-80]%	[160-180]%
Portugal	[…]	[…]	[…]	[…]	-[360-380]%	-[80-90]%	[…]	[…]		[…]		
Romania	[…]	[…]	[…]	[…]	-[1640-1660]%	-[90-100]%	[…]	[…]	[…]	[…]	[60-70]%	[100-120]%
Slovakia	[…]	[…]	[…]	[…]	-[200-220]%	-[70-80]%	[…]	[…]	[…]	[…]	[70-80]%	[200-220]%
Slovenia	[…]	[…]	[…]	[…]	-[460-480]%	-[80-90]%	[…]	[…]	[…]	[…]	[30-40]%	[20-30]%
Spain							[…]	[…]	[…]	[…]	[50-60]%	[60-70]%
Sweden	[…]	[…]	[…]	[…]	-[80-90]%	-[50-60]%	[…]	[…]	[…]	[…]	[70-80]%	[180-200]%
U.K.	[…]	[…]	[…]	[…]	[10-20]%	-[10-20]%	[…]	[…]	[…]	[…]	[70-80]%	[180-200]%
All	[…]	[…]	[…]	[…]	**[20-30]%**	**[0-5]%**	[…]	[…]	[…]	[…]	**[70-80]%**	**[160-180]%**

* Based on benchmark margin of 23% (EBITDA benchmark)

Annex Table 3: Profitability Analysis for Lanvis

	2012						2013-2019					
Country	**Volumes ('000 SU)**	**Net Sales ('000 €)**	**Avg. Price (€/SU)**	**Avg. Cost (€/SU)**	**% EBITDA Margins**	**% Excess over "Cost Plus"***	**Volumes ('000 SU)**	**Net Sales ('000 €)**	**Avg. Price (€/SU)**	**Avg. Cost (€/SU)**	**% EBITDA Margins**	**% Excess over "Cost Plus"***
Austria	[…]	[…]	[…]	[…]	-[340-360]%	-[80-90]%	[…]	[…]	[…]	[…]	[50-60]%	[60-70]%
Belgium	[…]	[…]	[…]	[…]	-[220-240]%	-[70-80]%	[…]	[…]	[…]	[…]	-[5-10]%	-[20-30]%
Bulgaria							[…]	[…]	[…]	[…]	[50-60]%	[50-60]%
Croatia												
Cyprus	[…]	[…]	[…]	[…]	-[100-120]%	-[60-70]%						
Czech Rep.	[…]	[…]	[…]	[…]	-[440-460]%	-[80-90]%	[…]	[…]	[…]	[…]	[30-40]%	[10-20]%
Denmark	[…]	[…]	[…]	[…]	[40-50]%	[30-40]%	[…]	[…]	[…]	[…]	[50-60]%	[60-70]%
Estonia							[…]	[…]	[…]	[…]	-[40-50]%	-[40-50]%
Finland	[…]	[…]	[…]	[…]	-[10-20]%	-[30-40]%	[…]	[…]	[…]	[…]	[30-40]%	[20-30]%
France	[…]	[…]	[…]	[…]	[0-5]%	-[20-30]%	[…]	[…]	[…]	[…]	[40-50]%	[40-50]%
Germany	[…]	[…]	[…]	[…]	-[50-60]%	-[40-50]%	[…]	[…]	[…]	[…]	[50-60]%	[80-90]%
Greece												
Hungary												
Iceland												
Ireland	[…]	[…]	[…]	[…]	-[20-30]%	-[30-40]%	[…]	[…]	[…]	[…]	[30-40]%	[10-20]%
Latvia	[…]	[…]	[…]	[…]	-[200-220]%	-[70-80]%	[…]	[…]	[…]	[…]	-[10-20]%	-[30-40]%
Lithuania	[…]	[…]	[…]	[…]	-[140-160]%	-[70-80]%	[…]	[…]	[…]	[…]	-[10-20]%	-[30-40]%
Malta												
Netherlands	[…]	[…]	[…]	[…]	[5-10]%	-[10-20]%	[…]	[…]	[…]	[…]	[30-40]%	[10-20]%
Norway	[…]	[…]	[…]	[…]	[40-50]%	[30-40]%	[…]	[…]	[…]	[…]	[40-50]%	[30-40]%
Poland		[…]					[…]	[…]	[…]	[…]	[50-60]%	[80-90]%
Portugal	[…]	[…]	[…]	[…]	[10-20]%	-[10-20]%	[…]	[…]	[…]	[…]	[90-100]%	[1240-1260]%
Romania							[…]	[…]	[…]	[…]	[20-30]%	[0-5]%
Slovakia	[…]	[…]	[…]	[…]	-[260-280]%	-[80-90]%	[…]	[…]	[…]	[…]	[5-10]%	-[10-20]%
Slovenia							[…]	[…]	[…]	[…]	[20-30]%	[5-10]%
Spain							[…]	[…]	[…]	[…]	[30-40]%	[20-30]%
Sweden	[…]	[…]	[…]	[…]	-[50-60]%	-[40-50]%	[…]	[…]	[…]	[…]	[50-60]%	[80-90]%
U.K.	[…]	[…]	[…]	[…]	[50-60]%	[70-80]%	[…]	[…]	[…]	[…]	[50-60]%	[70-80]%
All	[…]	[…]	[…]	[…]	**-[20-30]%**	**-[40-50]%**	[…]	[…]	[…]	[…]	**[40-50]%**	**[40-50]%**

* Based on benchmark margin of 23% (EBITDA benchmark)

Annex Table 4: Profitability Analysis for Leukeran

	2012						2013-2019					
Country	**Volumes ('000 SU)**	**Net Sales ('000 €)**	**Avg. Price (€/SU)**	**Avg. Cost (€/SU)**	**% EBITDA Margins**	**% Excess over "Cost Plus"***	**Volumes ('000 SU)**	**Net Sales ('000 €)**	**Avg. Price (€/SU)**	**Avg. Cost (€/SU)**	**% EBITDA Margins**	**% Excess over "Cost Plus"***
Austria	[…]	[…]	[…]	[…]	-[80-90]%	-[50-60]%	[…]	[…]	[…]	[…]	[70-80]%	[200-240]%
Belgium	[…]	[…]		[…]			[…]	[…]	[…]	[…]	[80-90]%	[340-360]%
Bulgaria	[…]	[…]	[…]	[…]	-[10-20]%	-[30-40]%	[…]	[…]	[…]	[…]	[5-10]%	-[10-20]%
Croatia												
Cyprus	[…]	[…]	[…]	[…]	-[200-220]%	-[70-80]%	[…]	[…]	[…]	[…]	-[140-160]%	-[70-80]%
Czech Rep.	[…]	[…]	[…]	[…]	-[140-160]%	-[60-70]%	[…]	[…]	[…]	[…]	[70-80]%	[180-200]%
Denmark	[…]	[…]	[…]	[…]	-[10-20]%	-[30-40]%	[…]	[…]	[…]	[…]	[70-80]%	[140-160]%
Estonia	[…]	[…]	[…]	[…]	-[100-120]%	-[60-70]%	[…]	[…]	[…]	[…]	-[20-30]%	-[30-40]%
Finland	[…]	[…]	[…]	[…]	-[100-120]%	-[60-70]%	[…]	[…]	[…]	[…]	[70-80]%	[240-260]%
France												
Germany	[…]	[…]	[…]	[…]	[5-10]%	-[10-20]%	[…]	[…]	[…]	[…]	[70-80]%	[260-280]%
Greece	[…]	[…]	[…]	[…]	[20-30]%	-[0-5]%	[…]	[…]	[…]	[…]	[80-90]%	[300-320]%
Hungary	[…]	[…]		[…]			[…]	[…]	[…]	[…]	[70-80]%	[200-220]%
Iceland							[…]	[…]		[…]		
Ireland	[…]	[…]	[…]	[…]	-[70-80]%	-[50-60]%	[…]	[…]	[…]	[…]	[60-70]%	[90-100]%
Latvia	[…]	[…]	[…]	[…]	-[80-90]%	-[50-60]%	[…]	[…]	[…]	[…]	[40-50]%	[30-40]%
Lithuania	[…]	[…]	[…]	[…]	-[50-60]%	-[50-60]%	[…]	[…]	[…]	[…]	[70-80]%	[240-260]%
Malta	[…]	[…]	[…]	[…]	-[180-200]%	-[70-80]%	[…]	[…]	[…]	[…]	[0-5]%	-[20-30]%
Netherlands	[…]	[…]	[…]	[…]	[30-40]%	[10-20]%	[…]	[…]	[…]	[…]	[80-90]%	[280-300]%
Norway	[…]	[…]	[…]	[…]	-[40-50]%	-[40-50]%	[…]	[…]	[…]	[…]	[50-60]%	[80-90]%
Poland	[…]	[…]	[…]	[…]	[70-80]%	[140-160]%	[…]	[…]	[…]	[…]	[70-80]%	[220-240]%
Portugal	[…]	[…]	[…]	[…]	-[540-560]%	-[80-90]%	[…]	[…]	[…]	[…]	-[380-400]%	-[80-90]%
Romania	[…]	[…]	[…]	[…]	-[520-540]%	-[80-90]%	[…]	[…]	[…]	[…]	[60-70]%	[100-120]%
Slovakia	[…]	[…]	[…]	[…]	-[70-80]%	-[50-60]%	[…]	[…]	[…]	[…]	[50-60]%	[70-80]%
Slovenia	[…]	[…]	[…]	[…]	-[20-30]%	-[30-40]%	[…]	[…]	[…]	[…]	[50-60]%	[70-80]%
Spain							[…]	[…]	[…]	[…]	[60-70]%	[120-140]%
Sweden	[…]	[…]	[…]	[…]	-[140-160]%	-[60-70]%	[…]	[…]	[…]	[…]	[70-80]%	[220-240]%
U.K.	[…]	[…]	[…]	[…]	[30-40]%	[10-20]%	[…]	[…]	[…]	[…]	[80-90]%	[320-340]%
All	[…]	[…]	[…]	[…]	**[0-5]%**	**-[20-30]%**	[…]	[…]	[…]	[…]	[70-80]**%**	**[200-220]%**

* Based on benchmark margin of 23% (EBITDA benchmark)

Annex Table 5: Profitability Analysis for Myleran

	2012						2013-2019					
Country	**Volumes ('000 SU)**	**Net Sales ('000 €)**	**Avg. Price (€/SU)**	**Avg. Cost (€/SU)**	**% EBITDA Margins**	**% Excess over "Cost Plus"***	**Volumes ('000 SU)**	**Net Sales ('000 €)**	**Avg. Price (€/SU)**	**Avg. Cost (€/SU)**	**% EBITDA Margins**	**% Excess over "Cost Plus"***
Austria	[…]	[…]	[…]	[…]	-[120-140]%	-[60-70]%	[…]	[…]	[…]	[…]	[70-80]%	[160-180]%
Belgium	[…]	[…]	[…]	[…]	-[800-820]%	-[90-100]%	[…]	[…]	[…]	[…]	[80-90]%	[420-440]%
Bulgaria												
Croatia												
Cyprus												
Czech Rep.	[…]	[…]	[…]	[…]	-[300-320]%	-[80-90]%	[…]	[…]	[…]	[…]	[70-80]%	[200-220]%
Denmark	[…]	[…]	[…]	[…]	[50-60]%	[50-60]%	[…]	[…]	[…]	[…]	[80-90]%	[280-300]%
Estonia	[…]	[…]	[…]	[…]	-[80-90]%	-[50-60]%	[…]	[…]	[…]	[…]	[70-80]%	[160-180]%
Finland							[…]	[…]	[…]	[…]	[70-80]%	[240-260]%
France	[…]	[…]	[…]	[…]	-[360-380]%	-[80-90]%	[…]	[…]	[…]	[…]	[40-50]%	[30-40]%
Germany	[…]	[…]	[…]	[…]	[50-60]%	[70-80]%	[…]	[…]	[…]	[…]	[80-90]%	[340-360]%
Greece												
Hungary												
Iceland							[…]	[…]	[…]	[…]	[10-20]%	-[5-10]%
Ireland	[…]	[…]	[…]	[…]	-[180-200]%	-[70-80]%	[…]	[…]	[…]	[…]	[50-60]%	[80-90]%
Latvia												
Lithuania	[…]	[…]	[…]	[…]	-[80-90]%	-[50-60]%	[…]	[…]	[…]	[…]	[70-80]%	[190-200]%
Malta												
Netherlands	[…]	[…]	[…]	[…]	[30-40]%	[20-30]%	[…]	[…]	[…]	[…]	[70-80]%	[260-280]%
Norway							[…]	[…]	[…]	[…]	[80-90]%	[320-340]%
Poland	[…]	[…]	[…]	[…]	[10-20]%	-[5-10]%	[…]	[…]	[…]	[…]	[60-70]%	[120-140]%
Portugal	[…]	[…]	[…]	[…]	-[940-960]%	-[90-100]%	[…]	[…]	[…]	[…]	-[2200-2220]%	-[90-100]%
Romania								[…]				
Slovakia	[…]	[…]	[…]	[…]	-[50-60]%	-[40-50]%	[…]	[…]	[…]	[…]	[70-80]%	[240-280]%
Slovenia		[…]					[…]	[…]	[…]	[…]	[60-70]%	[90-100]%
Spain							[…]	[…]	[…]	[…]	[60-70]%	[120-140]%
Sweden	[…]	[…]	[…]	[…]	-[560-580]%	-[80-90]%	[…]	[…]	[…]	[…]	[80-90]%	[300-320]%
U.K.	[…]	[…]	[…]	[…]	-[10-20]%	-[30-40]%	[…]	[…]	[…]	[…]	[80-90]%	[540-560]%
All	[…]	[…]	[…]	[…]	**[0-5]%**	**-[20-30]%**	[…]	[…]	[…]	[…]	**[80-90]%**	**[260-280]%**

* Based on benchmark margin of 23% (EBITDA benchmark)

Annex Table 6: Profitability Analysis for Purinethol

	2012						2013-2019					
Country	**Volumes ('000 SU)**	**Net Sales ('000 €)**	**Avg. Price (€/SU)**	**Avg. Cost (€/SU)**	**% EBITDA Margins**	**% Excess over "Cost Plus"***	**Volumes ('000 SU)**	**Net Sales ('000 €)**	**Avg. Price (€/SU)**	**Avg. Cost (€/SU)**	**% EBITDA Margins**	**% Excess over "Cost Plus"***
Austria	[…]	[…]	[…]	[…]	[70-80]%	[140-160]%	[…]	[…]	[…]	[…]	[80-90]%	[480-500]%
Belgium	[…]	[…]	[…]	[…]	-[20-30]%	-[30-40]%	[…]	[…]	[…]	[…]	[80-90]%	[420-440]%
Bulgaria	[…]	[…]	[…]	[…]	-[70-80]%	-[50-60]%	[…]	[…]	[…]	[…]	[20-30]%	-[0-5]%
Croatia												
Cyprus	[…]	[…]	[…]	[…]	-[70-80]%	-[50-60]%						
Czech Rep.	[…]	[…]	[…]	[…]	-[120-140]%	-[60-70]%	[…]	[…]	[…]	[…]	[30-40]%	[10-20]%
Denmark	[…]	[…]	[…]	[…]	[70-80]%	[180-200]%	[…]	[…]	[…]	[…]	[80-90]%	[560-580]%
Estonia	[…]	[…]	[…]	[…]	-[300-320]%	-[80-90]%	[…]	[…]	[…]	[…]	[20-30]%	[0-5]%
Finland												
France	[…]	[…]	[…]	[…]	-[60-70]%	-[50-60]%	[…]	[…]	[…]	[…]	[80-90]%	[340-360]%
Germany	[…]	[…]	[…]	[…]	[90-100]%	[700-720]%	[…]	[…]	[…]	[…]	[80-90]%	[380-400]%
Greece	[…]	[…]	[…]	[…]	[30-40]%	[20-30]%	[…]	[…]	[…]	[…]	[70-80]%	[240-260]%
Hungary												
Iceland							[…]	[…]	[…]	[…]	[50-60]%	[70-80]%
Ireland	[…]	[…]	[…]	[…]	[50-60]%	[70-80]%	[…]	[…]	[…]	[…]	[80-90]%	[620-640]%
Latvia	[…]	[…]	[…]	[…]	-[280-300]%	-[80-90]%	[…]	[…]	[…]	[…]	-[240-260]%	-[70-80]%
Lithuania	[…]	[…]	[…]	[…]	-[90-100]%	-[60-70]%	[…]	[…]	[…]	[…]	[40-50]%	[40-50]%
Malta							[…]	[…]	[…]	[…]	[90-100]%	[900-920]%
Netherlands	[…]	[…]	[…]	[…]	[70-80]%	[180-200]%	[…]	[…]	[…]	[…]	[80-90]%	[480-500]%
Norway	[…]	[…]	[…]	[…]	[60-70]%	[120-140]%	[…]	[…]	[…]	[…]	[80-90]%	[320-340]%
Poland												
Portugal	[…]	[…]	[…]	[…]	[40-50]%	[50-60]%	[…]	[…]	[…]	[…]	[80-90]%	[400-420]%
Romania	[…]	[…]	[…]	[…]	-[240-260]%	-[70-80]%	[…]	[…]	[…]	[…]	[60-70]%	[100-120]%
Slovakia	[…]	[…]	[…]	[…]	-[30-40]%	-[40-50]%	[…]	[…]	[…]	[…]	[50-60]%	[50-60]%
Slovenia	[…]	[…]	[…]	[…]	-[760-780]%	-[90-100]%	[…]	[…]	[…]	[…]	[40-50]%	[50-60]%
Spain							[…]	[…]	[…]	[…]	[50-60]%	[70-80]%
Sweden	[…]	[…]	[…]	[…]	[30-40]%	[10-20]%	[…]	[…]	[…]	[…]	[80-90]%	[600-620]%
U.K.	[…]	[…]	[…]	[…]	[80-90]%	[340-360]%	[…]	[…]	[…]	[…]	[80-90]%	[480-500]%
All	[…]	[…]	[…]	[…]	**[50-60]%**	**[80-90]%**	[…]	[…]	[…]	[…]	[80-90]**%**	**[400-420]%**

* Based on benchmark margin of 23% (EBITDA benchmark)

Effective date of actual price increase	EEA Member State	Products (SKU)
1 May 2012	Germany	Alkeran IV (50mg/17ml); Alkeran (tab 2mg x 25); Alkeran (tab 2mg x 50); Leukeran (tab 2mg x 25); Leukeran (tab 2mg x 50); Myleran (tab 2mg x 100); Myleran (tab 2mg x 25); Purinethol (tab 50mg x 25); Lanvis (40mg x 25)
25 May 2012	Lithuania *(Official list prices)*	Alkeran (tab 2mg x 25); Leukeran (tab 2mg x 25); Myleran (tab 2mg x 100); Purinethol (tab 50mg x 25); Lanvis (40mg x 25)
1 July 2012	Estonia *(Reimbursed prices subject to revisions)*	Alkeran (tab 2mg x 25); Leukeran (tab 2mg x 25); Myleran (tab 2mg x 100); Purinethol (tab 50mg x 25); Lanvis (40mg x 25)
	Latvia	Alkeran (tab 2mg x 25); Leukeran (tab 2mg x 25); Purinethol (tab 50mg x 25); Lanvis (40mg x 25)
	Poland *(Reimbursed hospital prices)*	Alkeran (tab 2mg x 25); Leukeran (tab 2mg x 25); Myleran (tab 2mg x 100); Lanvis (40mg x 25)
1 August 2012	UK	Alkeran IV (50mg/17ml); Alkeran (tab 2mg x 25); Leukeran (tab 2mg x 25); Myleran (tab 2mg x 25); Purinethol (tab 50mg x 25); Lanvis (40mg x 25)
1 November 2012	Poland *(Reimbursed retail prices)*	Alkeran (tab 2mg x 25); Leukeran (tab 2mg x 25); Myleran (tab 2mg x 25); Lanvis (40mg x 25)
1 December 2012	Sweden	Alkeran IV (50mg/17ml); Alkeran (tab 2mg x 25); Alkeran (tab 2mg x 50); Leukeran (tab 2mg x 25); Leukeran (tab 2mg x 50); Myleran (tab 2mg x 100); Purinethol (tab 50mg x 25); Lanvis (40mg x 25)
1 January 2013	Austria	Alkeran (tab 2mg x 25); Leukeran (tab 2mg x 25); Myleran (tab 2mg x 100); Purinethol (tab 50mg x 25); Lanvis (40mg x 25)
	Slovakia	Alkeran IV (50mg/17ml); Alkeran (tab 2mg x 25); Leukeran (tab 2mg x 25); Myleran (tab 2mg x 100); Purinethol (tab 50mg x 25); Lanvis (40mg x 25)
1 March 2013	Ireland *(Official list prices & reimbursed prices)*	Alkeran IV (50mg/17ml); Alkeran (tab 2mg x 25); Leukeran (tab 2mg x 25); Leukeran (tab 2mg x 50); Purinethol (tab 50mg x 25); Lanvis (40mg x 25)
	Denmark	Alkeran (tab 2mg x 25); Leukeran (tab 2mg x 25)
13 March 2013	Belgium *(Official list prices)*	Alkeran IV (50mg/17ml); Alkeran (tab 2mg x 25); Leukeran (tab 2mg x 50); Myleran (tab 2mg x 100); Purinethol (tab 50mg x 25); Lanvis (40mg x 25)
1 June 2013	Czechia *(Maximum list prices subject to ex-officio revisions)*	Alkeran IV (50mg/17ml); Alkeran (tab 2mg x 25); Leukeran (tab 2mg x 25); Myleran (tab 2mg x 100); Lanvis (40mg x 25)
13 June 2013	France	Alkeran (tab 2mg x 50); Purinethol (tab 50mg x25)
15 June 2013	Norway	Alkeran (tab 2mg x 25); Leukeran (tab 2mg x 25); Purinethol (tab 50mg x 25)
11 July 2013	France	Lanvis (40mg x 25)
26 July 2013	France	Myleran (tab 2mg x 25)
1 September 2013	Slovenia	Leukeran (tab 2mg x 25); Myleran (tab 2mg x 100); Lanvis (40mg x 25)
1 October 2013	Finland	Alkeran (tab 2mg x 25); Leukeran (tab 2mg x 25)
	Netherlands	Alkeran IV (50mg/17ml); Alkeran (tab 2mg x 25); Leukeran (tab 2mg x 25); Myleran (tab 2mg x 100); Purinethol (tab 50mg x 25); Lanvis (40mg x 25)

Effective date of actual price increase	EEA Member State	Products (SKU)
25 November 2013	Belgium *(Official list prices)*	Alkeran IV (50mg/10ml); Alkeran (tab 2mg x 25); Leukeran (tab 2mg x 50); Myleran (tab 2mg x 100); Purinethol (tab 50mg x 25); Lanvis (40mg x 25)
6 December 2013	Slovenia	Alkeran (tab 2mg x 25); Purinethol (tab 50mg x 25)
1 January 2014	Iceland	Alkeran (tab 2mg x 25); Leukeran (tab 2mg x 25); Myleran (tab 2mg x 100); Purinethol (tab 50mg x 25)
	Romania	Alkeran (tab 2mg x 25); Leukeran (tab 2mg x 25); Myleran (tab 2mg x 25); Myleran (tab 2mg x 100); Purinethol (tab 50mg x 25); Lanvis (40mg x 25)
4 February 2014	Czechia *(Reimbursed prices)*	Lanvis (40mg x 25)
1 April 2014	Netherlands	Alkeran IV (50mg); Alkeran (tab 2mg x 25); Leukeran (tab 2mg x 25); Myleran (tab 2mg x 100); Purinethol (tab 50mg x 25); Lanvis (40mg x 25)
15 April 2014	Czechia *(Reimbursed prices)*	Alkeran (tab 2mg x 25); Leukeran (tab 2mg x 25)
23 April 2014	Czechia *(Reimbursed prices)*	Myleran (tab 2mg x 100)
1 May 2014	Belgium *(Reimbursed prices)*	Alkeran IV (50mg/17ml); Alkeran (tab 2mg x 25); Leukeran (tab 2mg x 50); Myleran (tab 2mg x 100); Purinethol (tab 50mg x 25); Lanvis (40mg x 25)
	Finland	Alkeran (tab 2mg x 25); Leukeran (tab 2mg x 25)
30 May 2014	Slovenia	Myleran (tab 2mg x 100)
12 June 2014	Czech Republic	Alkeran IV (50mg/17ml)
1 August 2014	Luxembourg	Alkeran IV (50mg/10ml); Alkeran (tab 2mg x 25); Leukeran (tab 2mg x 50); Myleran (tab 2mg x 100); Purinethol (tab 50mg x 25)
[Q4 2015]	Bulgaria	Leukeran (tab 2mg x 25); Purinethol (tab 50mg x 25)
[Q4 2016]	Lithuania *(Net Wholesaler prices & reimbursed prices)*	Alkeran (tab 2mg x 25); Leukeran (tab 2mg x 25); Myleran (tab 2mg x 100); Purinethol (tab 50mg x 25); Lanvis (40mg x 25)
[Q1 2017]	Estonia *(Net Wholesaler prices)*	Alkeran (tab 2mg x 25); Leukeran (tab 2mg x 25); Myleran (tab 2mg x 100); Purinethol (tab 50mg x 25); Lanvis (40mg x 25)
[Q1 2019]	Romania	Myleran (tab 2mg x 100)

Source: Confidential Annex 1 of Aspen submission dated 5 February 2019.