

Case AT.40394 – Aspen**COMMITMENTS TO THE EUROPEAN COMMISSION**

- 1) On 15 May 2017, the European Commission initiated formal antitrust proceedings against Aspen under case number AT.40394 – Aspen.
- 2) In accordance with Article 9 of Council Regulation (EC) No 1/2003, Aspen hereby offers these Commitments with a view to addressing the Commission’s competition concerns as expressed in its Preliminary Assessment for the period covered by the Commitments and enabling the Commission to adopt a decision making those Commitments binding on Aspen (the “**Commitment Decision**”).
- 3) Consistent with Article 9 of Regulation 1/2003, these Commitments do not constitute an acknowledgement that Aspen has infringed EU competition law. Aspen acts on the condition that, by accepting these Commitments, the Commission will terminate the proceedings in case AT.40394 without concluding whether or not there has been an infringement of competition law.
- 4) This text shall be interpreted in light of the Preliminary Assessment, the Commitment Decision, the general framework of European Union law, and in particular in light of Articles 101 and 102 TFEU and Council Regulation (EC) No 1/2003.

Section A: Definitions

- 5) For the purpose of the Commitments, the following terms shall have the following meaning:

Affiliated Undertakings: undertakings controlled by Aspen Pharmacare Holdings Ltd, whereby the notion of control shall be interpreted pursuant to Article 3 of Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings and in light of the Commission Consolidated Jurisdictional Notice under that regulation.

API: Active Pharmaceutical Ingredient.

Appropriate Beneficiary: Person(s) identified in Appendix 1 to the Commitments which will receive the Transitory Rebates or Co-payment Rebates pursuant to paragraph 9) below.

Aspen: Aspen Pharmacare Holdings Ltd¹ including Aspen Pharma Ireland Limited² (which are the addressees of the Commission Decision), together with all Affiliated Undertakings, including but not limited to Aspen Global Incorporated³, Aspen Pharma Trading Limited⁴,

¹ A company incorporated in the Republic of South Africa.

² A company incorporated in Ireland.

³ A company incorporated in Mauritius.

⁴ A company incorporated in Ireland.

Aspen Europe GmbH⁵ (including its branches in various Member States), Aspen Bad Oldesloe GmbH⁶ and Aspen Healthcare FZ LLC⁷.

Bad Debts: any amounts invoiced for the Relevant Products that subsequently prove to be uncollectable due to the refusal or inability of the customer to pay the amount owing or part thereof.

Co-payment Rebate: shall have the meaning as defined in paragraph 9) v) below of these Commitments.

Commercialise: the marketing, distribution and/or selling of a Relevant Product in the Relevant Country by Aspen or its agents, independent distributors or logistic service providers with which Aspen has a contractual relation (“**Agents**”). “**Commercialised**” and “**Commercialisation**” shall be construed accordingly.

Commission: the European Commission.

Commitment Decision: the Commission’s decision pursuant to Art. 9 Reg. 1/2003 in case AT.40394 accepting the Commitments submitted hereby.

Commitment Period: a period of ten (10) years from the Entry Into Force.

Commitments: the commitments recorded in this document.

Conflict of Interest: any conflict of interest that impairs the Trustee’s objectivity and independence in discharging its duties under the Commitments.

Cost of Goods: (i) in respect of Relevant Products which are manufactured or supplied by third parties, the costs to Aspen of purchasing the Relevant Products (including, in the case of toll manufactured Relevant Products, the separate costs of API and conversion to finished dose form Relevant Products) from a third party manufacturer or supplier, plus [...] of such costs to cover freight, import and export duties and insurance expenses associated with the transportation of the Relevant Products from the third party manufacturer or supplier to Aspen (together the “**Purchased COGS**”) and (ii) in respect of Relevant Products which are manufactured by Aspen, the lower of either their Standard Cost or the Purchased COGS of the same Relevant Products as invoiced in the year prior to the move of their production to Aspen (the “**Benchmark Year Costs**”). As an exception to the previous rule, should the Standard Cost increase above the Benchmark Year Costs in the second year, for the application of paragraph 46) increased costs will only be taken into account to the extent the increases (above those Benchmark Year Costs) are based on increases in the cost of input materials and/or services acquired from third parties for the production of the Relevant Products and/or, up to the Central Bank’s official rate of inflation in the country of the relevant Aspen manufacturing facility in the case of labour

⁵ A company incorporated in Germany.

⁶ A company incorporated in Germany.

⁷ A company incorporated in the United Arab Emirates.

and overhead increases for the production of Relevant Products, all as required for the production of the Relevant Products.

Direct Costs: the Costs of Goods, Distribution Costs and the cost of Bad Debts.

Distribution Costs: fees and expenses paid by Aspen to logistic service providers associated with the in-market distribution of the Relevant Products in the Relevant Countries.

EBITDA: Net Sales of the Relevant Product in the Relevant Country, less Direct Costs and an allocation of Indirect Costs, in line with the methodology note on the allocation of Indirect Costs attached as Appendix 2 to the Commitments.

EBITDA Margin: EBITDA divided by Net Sales.

Effective Date: 1 October 2019.

Entry Into Force: the date when the Commitment Decision is notified to Aspen.

Event of Force Majeure: occurrence of (i) abnormal, unforeseeable and external circumstances and (ii) acts of God, limiting Aspen's ability to supply that are outside the control of Aspen and the consequences of which could not, despite the exercise by Aspen of all due care, have been avoided. The exercise of due care includes taking appropriate steps to guard against the consequences of abnormal, unforeseeable and external circumstances and acts of God without making unreasonable sacrifices.

Fall-back Recipient: shall have the meaning as defined in paragraph 9) iii) of these Commitments.

Financial Year ("FY"): Aspen's financial year that starts on 1 July of each calendar year and ends on 30 June of the following calendar year.

Foreign Pack: a pack of a Relevant Product originally manufactured for sale in a country other than the country in which it is ultimately placed on the market.⁸

Foreign Pack Sales: all sales of Foreign Packs directly by Aspen, or Aspen's Agents, in a Relevant Country in accordance with the applicable laws, regulations and guidelines of the Relevant Country.

Gross Price: the EUR price invoiced by Aspen to its customers for the Relevant Products in the Relevant Country net of value added and excise taxes, tariffs and duties, and other relevant taxes and relevant to the price reduction in Relevant Countries where the price reduction is not implemented by the reduction of List Prices.

⁸ The import by Aspen of the Relevant Products in the form of Foreign Packs is based on the derogations provided in Directive 2001/83/EC or the EU-wide validity of marketing authorisations granted under Regulation (EC) No 726/2004. In the absence of such a marketing authorisation, the supply of Foreign Packs may be allowed by national authorities on an ad hoc basis for a certain number of units following requests from individual health personnel, hospitals or regional healthcare services.

Gross Sales: the aggregate of the gross EUR amount resulting from all invoices issued by Aspen to its customers for the Relevant Products in the Relevant Country.

Implementation Date: the date upon which the Reduced Net Prices enter into effect through selling at reduced Gross Prices, or an official reduction of List Prices, as appropriate for each Relevant Product.

Interest Rate: the amount of interest calculated based on the rate set by the European Central Bank (ECB) for its principal refinancing operations, as published in the C series of the *Official Journal of the European Union*, in force on the first calendar day of the relevant month, plus 1.5 percentage points.

Indirect Costs: the operating expenditures of entities within Aspen that provide services or undertake the management of, or are associated with, the sale of the Relevant Products in the Relevant Countries (including maintaining marketing authorisations) excluding depreciation, amortisation or impairment charges relating to tangible fixed assets or intangible assets.

Launch Product(s): shall have the meaning as defined in paragraph 12) of these Commitments.

List Price: where applicable, the unit price in EUR that has been approved by the Regulatory Authorities of the Relevant Countries for a Relevant Product and has been published in accordance with the laws and regulations of the same Relevant Country or otherwise applicable pursuant to the regulatory framework in that Relevant Country. The List Price does not correspond to the Net Price.

Net Price: Net Sales in EUR as received by Aspen in the previous Financial Year divided by quantity sold in the same Financial Year on a Relevant Product by Relevant Product and Relevant Country by Relevant Country basis. See also the definition of the Reduced Net Price.

Net Sales: Gross Sales in EUR, less,

- i) sales, value added and excise taxes, tariffs and duties, and other taxes directly relating to the sale of the Relevant Products in the Relevant Countries;
- ii) trade, quality and cash discounts, stocking allowances and rebates;
- iii) credits for billing errors, rejected products, damaged products, withdrawals, recalls or returns, net of amounts reimbursed to Aspen;
- iv) credits, charge backs and rebates, reimbursements, administrative fees, wholesaler fees for service and similar payments accrued or given to wholesalers or other distributors, buying groups, healthcare insurance carriers, pharmaceutical benefit management companies, health maintenance organisations, other healthcare institutions and organisations or other customers;
- v) freight, shipping and insurance expenses as invoiced to customers.

Person: includes any natural or legal person or association including a voluntary association and any similar entity in any Relevant Country.

Preliminary Assessment: the Commission's concerns as expressed in its Preliminary Assessment, dated 19 June 2020.

Reduced Net Price: the maximum EUR Net Price for a Relevant Product in a Relevant Country as received by Aspen pursuant to the Commitments. The Reduced Net Prices for each Relevant Product in each Relevant Country are set out in Table 1 below. The Reduced Net Price does not include fees and mark-ups attributable to distributors, pharmacies or other intermediaries. See also the definition of the Gross Price and the List Price, each of which are different from the Reduced Net Price.

Relaunch Product(s): shall have the meaning as defined in paragraph 11) of these Commitments.

Relevant Product or Relevant Products: Aspen's medicinal products containing the APIs chlorambucil, melphalan, mercaptopurine, busulfan and tioguanine, regardless of pack size, and solely relating to the dose forms as set out below, namely:

- i) **Alkeran tab:** medicinal product of Aspen containing melphalan as its sole API, in tablet form, sold and/or registered in the Relevant Countries. For the avoidance of doubt, Alkeran tab includes in particular: (i) Alkeran 2mg tablets 25s, (ii) Alkeran 2mg tablets 50s.
- ii) **Alkeran IV:** medicinal product of Aspen containing melphalan as its sole API, in injectable form, sold and/or registered in the Relevant Countries. For the avoidance of doubt, Alkeran IV includes in particular the pack of Alkeran 50mg including diluent INJ and Alkeran 50mg FD injection vial x 17 ml.
- iii) **Lanvis:** medicinal product of Aspen containing tioguanine as its sole API, in tablet form, sold and/or registered in the Relevant Countries. For the avoidance of doubt, Lanvis includes in particular Lanvis 40mg 25s.
- iv) **Leukeran:** medicinal product of Aspen containing chlorambucil as its sole API, in tablet form, sold and/or registered in the Relevant Countries. For the avoidance of doubt, Leukeran comprises in particular (i) Leukeran 2mg 25s and (ii) Leukeran 2mg 50s.
- v) **Myleran:** medicinal product of Aspen containing busulfan as its sole API, in tablet form, sold and/or registered in the Relevant Countries. For the avoidance of doubt, Myleran comprises in particular (i) Myleran 2mg 25s and (ii) Myleran 2mg 100s.
- vi) **Purinethol:** medicinal product of Aspen containing mercaptopurine as its sole API, in tablet form, sold and/or registered in the Relevant Countries. For the avoidance of doubt, Purinethol includes in particular Mercaptopurine 50mg 25s.

Regulatory Authority or Regulatory Authorities: the competent national pricing and reimbursement authority of each Relevant Country as relevant to paragraph 9) and the commitments identified therein and/or competent authority of each Relevant Country to receive Aspen's pricing applications as relevant to paragraph 7) i).

Relevant Country or Relevant Countries: the Member States of the European Economic Area (EEA) except Italy where a Relevant Product(s) is Commercialised by Aspen on or as of the Effective Date, or at any time during the Commitment Period.

Residual Fall-back Recipient: shall have the meaning as defined in paragraph 9) vi) of these Commitments.

Standard Cost: in respect of a Relevant Product manufactured by Aspen, the fully-absorbed cost of manufacture as calculated in a manner consistent with International Financial Reporting Standards and the standard costing methodology employed by Aspen for other products, including and without limitation the cost of materials, direct labour, ordinary course quality assurance costs, equipment maintenance costs and other costs variable with production plus a reasonable allocation of the relevant manufacturing sites fixed overheads, excluding any depreciation, impairment or amortisation (together “**Manufactured Cost**”) plus [...] of such Manufactured Cost to cover freight, import and export duties and insurance expenses associated with the transportation of the Relevant Product from the manufacturing site to the market. For clarity, Aspen’s application of the costing methodology as set out in IFRS (International Accounting Standard 2 “Inventories”, paragraph 13) means that the allocation of the relevant manufacturing site’s fixed production overheads to the costs of conversion is based on the normal capacity of the relevant production facility. Normal capacity is the production expected to be achieved on average over a number of periods or seasons under normal circumstances, taking into account the loss of capacity resulting from planned maintenance.

Supplementary Supply Commitment Period: a period of five (5) years from the expiry of the Supply Commitment Period.

Supply Commitment Period: a period of five (5) years from the Entry Into Force.

Transitory Period and Transitory Rebate or Transitory Rebates: shall have the meaning as defined in paragraph 9) of these Commitments.

Section B: Price Commitments

B.1 – Net Price Reduction

- 6) Aspen undertakes to implement Reduced Net Prices not higher than those set out in Table I below for each Relevant Product in each Relevant Country for the relevant dosage form and pack size identified. For Relevant Countries where Aspen sells the Relevant Product(s) in a currency other than EUR, the Reduced Net Prices in Table I are converted into the local currency on the Entry Into Force.⁹ These converted Reduced Net Prices shall be the relevant Reduced Net Prices for the Commitment Period. Aspen shall not, directly or indirectly, refer to these Commitments in any of its communications, in particular with national authorities as a reason for any price increase request. Aspen is free to price below the Reduced Net Prices. The Reduced Net Prices will take effect as of the Effective Date and will remain in effect for the duration of the Commitment Period, i.e. a period of ten (10) years from the Entry Into Force of the Commitments.

Table I: Reduced Net Prices for the Relevant Products^{10 11} (EUR)

Relevant Country / Product (pack size)	Alkeran IV	Alkeran tab 25	Alkeran tab 50	Lanvis 25	Leukeran 25	Leukeran 50	Myleran 25	Myleran 100	Purinethol 25
Austria	28.65	27.06	-	106.00	17.45	-	-	91.75	9.76
Belgium	32.33	23.48	-	76.30	-	19.31	-	52.16	11.41
Bulgaria	-	-	-	70.51	8.48	-	-	-	13.03
Czech Republic	27.73	46.80	-	106.00	16.25	-	-	86.51	22.60
Denmark	-	38.53	-	93.43	34.55	-	-	91.96	21.28
Estonia	23.71*	51.76	-	-	38.70	-	-	76.95	36.00
Finland	33.11	26.30	-	72.51	13.26	-	-	64.44	-
France	24.15	-	25.38	69.26	-	-	38.85	-	8.32
Germany	30.27	23.39	31.97	75.85	13.08	18.93	23.90	48.95	11.46
Greece	-	18.83	-	-	14.83	-	-	-	-
Hungary	36.00*	-	-	-	13.26*	-	-	-	-
Iceland	27.53	18.55	-	-	34.55*	-	-	91.96	36.00
Ireland	36.00	47.17	-	-	26.40	-	-	-	13.41
Latvia	-	50.99	-	-	14.23	-	-	-	-
Lithuania	-	27.06*	-	85.78*	38.70	-	-	80.12	23.72
Malta	-	-	-	-	-	-	-	-	6.51
Netherlands	26.22	16.38	-	55.21	10.28	-	-	61.97	7.79

⁹ The local currency Reduced Net Prices will be determined on the Entry Into Force based on the average exchange rate set by the European Central Bank (ECB), as published in the ECB's website, in force during the last completed calendar month preceding the Entry Into Force. For the avoidance of doubt, changes in the exchange rate after the Entry Into Force are not taken into account.

¹⁰ Prices of Relevant Products and/or pack sizes (re)-commercialised as of Financial Year 2020 and determined based on paragraphs 11) to 14), as appropriate, are identified with an asterisk in this Table I.

¹¹ The Reduced Net Price does not include fees and mark-ups attributable to distributors, pharmacies or other intermediaries, see definition of Reduced Net Prices.

Relevant Country / Product (pack size)	Alkeran IV	Alkeran tab 25	Alkeran tab 50	Lanvis 25	Leukeran 25	Leukeran 50	Myleran 25	Myleran 100	Purinethol 25
Norway	-	21.26	-	85.78	22.88	-	-	63.99	13.44
Poland	23.71	23.05	-	85.50	16.34	-	38.07	75.77	-
Portugal	-	18.24	-	-	8.32	-	-	-	-
Romania	-	20.66	-	87.35	16.58	-	-	76.95*	8.66
Slovakia	27.66	51.76	-	106.00	38.70	-	-	91.75*	36.00
Slovenia	-	32.53	-	102.04	19.85	-	32.23	49.93	36.00
Spain	23.71*	23.05*	31.91	69.26*	-	22.85	-	60.72	12.07
Sweden	23.82	20.02	27.27	67.83	17.63	26.45	-	79.75	11.39
United Kingdom	26.71	16.52	-	76.55	11.18	-	14.46	-	9.44

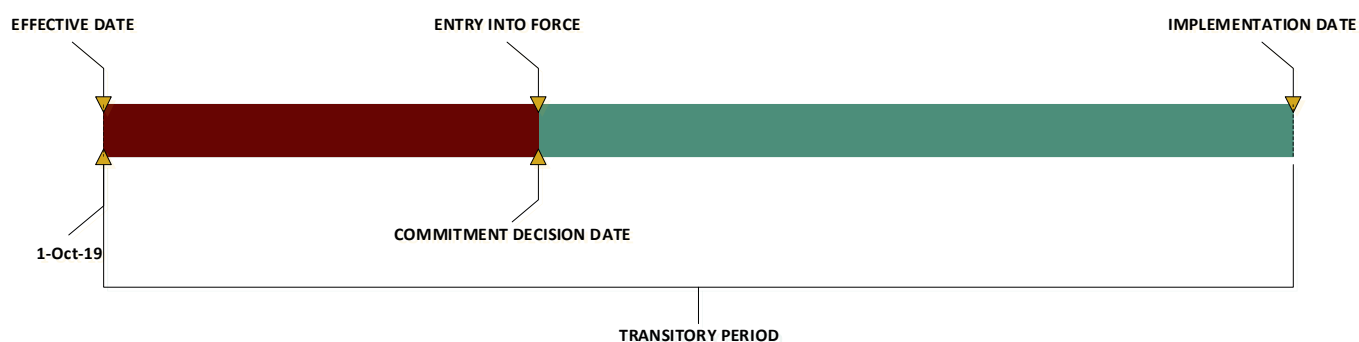
- 7) In order to achieve the Reduced Net Prices Aspen undertakes to:
- i) where a List Price exists, within one week of the Entry Into Force, or as soon as possible thereafter under applicable regulatory procedures, submit applications to the Regulatory Authorities to reduce the List Prices of the Relevant Products in the Relevant Countries to the level identified in Appendix 3 in order to achieve the Reduced Net Prices. Aspen will submit applications to the Regulatory Authorities identified in Appendix 4, pursuant to the forms and procedures applicable under local laws and regulations. Aspen shall submit complete applications that include all elements required under local laws and immediately make any amendments or modifications requested by the Relevant Regulatory Authority and undertake all actions possible to proactively assist the relevant Regulatory Authority in order to achieve the Reduced Net Prices, and do everything possible to ensure the expedient reduction of the List Prices. Where feasible pursuant to local laws and procedures, Aspen will pursue an expedited process pursuant to the applicable laws and procedures. Aspen will immediately inform its Agents and customers of the approval of the new List Prices; or
 - ii) where a List Price does not exist (i.e. the Relevant Countries listed in Appendix 5) Aspen will reduce Gross Prices of the Relevant Products as soon as possible after the Entry Into Force to the level identified in Appendix 5 in order to achieve the Reduced Net Prices, subject to any pre-existing contractual/tender obligations.
 - iii) For the avoidance of doubt, during the period from the Effective Date until the Implementation Date, the provisions of paragraph 9) on Transitory Rebates will apply.
- 8) To ensure that price reductions implemented by Aspen are effectively passed-on to those who purchase or reimburse the Relevant Products, immediately upon Entry Into Force Aspen will use its best endeavours to amend the contracts with its Agents to include a clause whereby the Agents would commit to reduce their selling prices of the Relevant Products in line with or in proportion to the reduction of Aspen's Net Prices. Aspen commits to enforce such a clause in case of breach by its Agents.

B.2 – Transitory Rebate

- 9) To ensure that Aspen, as of the Effective Date, charges effectively no higher Net Prices than the Reduced Net Prices in Table I above, Aspen undertakes, for all Relevant Countries, to make a payment to each Appropriate Beneficiary (as listed in Appendix 1) in the amount of the difference between Aspen’s actual Net Sales and its hypothetical Net Sales had those same quantities been sold at the Reduced Net Prices for the Relevant Products in each Relevant Country (“**Transitory Rebate**”).

The Transitory Rebate shall be calculated based on the principles set out in this paragraph 9) and Appendix 1, and paid for the entire time period between the Effective Date and the Implementation Date (the “**Transitory Period**”). The payment made by Aspen to the Appropriate Beneficiary shall also include interest, calculated from the first day of the Transitory Period until full payment of the Transitory Rebate, both days inclusive. Such interest will be calculated using the Interest Rate and the assumption that, in the absence of specific data, the Transitory Rebate arose evenly over the Transitory Period. Consequently, all references in these Commitments to the payment of a Transitory Rebate include the payment of such interest.

The calculation of the Transitory Rebate is based on Aspen’s *sales* in each Relevant Country. For the avoidance of doubt, the calculation of the Transitory Rebate amount is therefore not based on the value of purchases or reimbursement by a given Appropriate Beneficiary, but rather Aspen’s realised sales revenues.¹² Further, for the avoidance of doubt, in the case of Foreign Pack Sales, the Transitory Rebate shall thus be accounted for and included by Aspen in the calculation of the Transitory Rebate in the Relevant Country or Countries where Aspen ultimately placed it on the market and generated revenues. In contrast, Relevant Products purchased by parallel traders are accounted for in the country where Aspen placed them for the first time on the market and not in the country where a parallel trader sells the product (i.e. the final destination of the parallel import).



¹² The amount of the Transitory Rebate and reimbursement amounts are not the same, because reimbursement amounts are based on prices that include also 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.

i) Notification obligations:

- (1) Immediately after Entry Into Force, Aspen will write to each Appropriate Beneficiary: (a) informing it that it is entitled to a Transitory Rebate; (b) making suitable suggestions on how to pay the Transitory Rebate within the time periods specified below; (c) informing it of the estimated amount of the Transitory Rebate; and (d) explaining that the final amount of the Transitory Rebate will depend on the date that the List Prices or the Gross Prices (as the case may be) are effectively reduced pursuant to paragraph 7).
- (2) On a Relevant Product-by-Relevant Product basis, immediately after the Implementation Date, Aspen will write to each Appropriate Beneficiary informing the latter of the amount of the Transitory Rebate as calculated by Aspen in accordance with this paragraph 9) and that the payment shall include interest and requesting confirmation of the modalities for payment.

ii) Time limits for payment:

the Transitory Rebate shall be paid within ninety (90) days after informing the Appropriate Beneficiary about the amount of the Transitory Rebate. This time limit can be extended by sixty (60) additional days subject to an extension request submitted by the Appropriate Beneficiary within the original ninety (90) day period. To the extent that Aspen does not receive instructions from the Appropriate Beneficiary for payment of the Transitory Rebate, it shall send written reminders to the Appropriate Beneficiary every thirty (30) days and a last written reminder ten (10) days before the end of the given period.

iii) Fall-back:

in the event that an Appropriate Beneficiary has not provided necessary instructions for some or all of the payment of a Transitory Rebate pursuant to paragraph 9) i), or if it is for other reasons not possible to pay all or part of a Transitory Rebate to the Appropriate Beneficiary within the time-limit foreseen in paragraph 9) ii) above, Aspen will notify the Regulatory Authority in the Relevant Country. If Aspen after thirty (30) days still has not received any instructions for payment to the Appropriate Beneficiary identified in Appendix 1 and if the Regulatory Authority has also not nominated an alternative recipient, Aspen will transfer any non-paid parts of the Transitory Rebate to the recipient identified in Appendix 1 as fall-back recipient (“**Fall-back Recipient**”). If the Regulatory Authority has nominated an alternative recipient pursuant to this paragraph 9)iii), Aspen will pay the Transitory Rebate instead to this alternative recipient, paragraph 9) being applied *mutatis mutandis*.

iv) Instalment in case of major delay:

if Aspen has not yet transferred the Transitory Rebate within one (1) year after the Entry Into Force of the Commitments, Aspen will send a letter to the respective Appropriate Beneficiaries offering to pay an instalment of the Transitory Rebate.

- v) **Co-payment:**
- for Germany and the Czech Republic, where patient co-payment for some of the Relevant Products exists, Aspen shall, within two (2) months of the Entry Into Force, according to the modalities set out in Appendix 1 for each of the two countries concerned, take appropriate steps to inform patients who made a co-payment during the Transitory Period that they are entitled to a portion of the Transitory Rebate (“**Co-payment Rebate**”). In its communication to patients, doctors (including oncologists/haematologists) and pharmacists, Aspen shall: (1) state the reasons for the Co-payment Rebate by reference to the Commission Decision and investigation; (2) explain the period for which the patients can claim payment of a Co-payment Rebate; (3) indicate the approximate amount of the Co-payment Rebate per pack to be paid; and (4) invite the patients concerned to make a claim for a payment of the Co-payment Rebate by Aspen within the applicable deadlines. Aspen’s communications shall comply with applicable national and EU rules on advertising of pharmaceutical prescription medicines. Aspen will take appropriate steps to communicate regular reminders to the patients who made co-payments to the extent permissible under applicable laws. To the extent Aspen has not received claim(s) eighteen (18) months after having taken first steps to inform the patients, Aspen will transfer any balance of the Co-payment Rebate to the specific Fall-back Recipient identified in Appendix 1. Should the Implementation Date be delayed, the period of eighteen (18) months will be prolonged accordingly to ensure that the patients will have a period of at least six (6) months from the Implementation Date to claim the Co-payment Rebate. Patients are entitled to claim a share of their Co-payment Rebate for a given period before the Implementation Date, without prejudice to claiming the remaining part of their Co-payment Rebate later.
- vi) **No exceeding revenues retained by Aspen:**
- under no circumstances will Aspen retain any revenues attributable to or resulting from the application of a price level that exceeds the Reduced Net Prices as from the Effective Date. Should the Trustee have established that the payment of the Transitory Rebate and Co-payment Rebate to the Appropriate Beneficiaries or the Fall-back Recipients pursuant to sub-clauses i) to v) has not been fully made, any remaining amount of the Transitory Rebate will be paid to the Residual Fall-back Recipient identified in section 2 of Appendix 1.
- vii) Aspen will immediately send copies of all its communications under paragraph 9) to the Trustee.
- 10) In the event that a Regulatory Authority does not approve the request to revise List Prices under paragraph 7) i) above for one or more of the Relevant Products, Aspen shall appeal such decision and in parallel Commercialise the Relevant Products in the Relevant Country to the extent allowed by applicable laws, at Gross Prices set at the level identified in Appendix 3 to achieve the Reduced Net Price, pursuant to paragraph 7) ii) of these Commitments. For the avoidance of doubt, pursuant to paragraph 9) above, Aspen will not retain any revenues attributable or resulting from the Regulatory Authority’s decision not to approve the request to revise List Prices.

B.3 – Commercialisation or re-commercialisation of new Relevant Products and/or new pack sizes

- 11) For those Relevant Products not Commercialised in a Relevant Country in Aspen's FY 2019 and between the end of FY2019 and the Effective Date, but Commercialised by Aspen in that Relevant Country before its FY2019, if Aspen were to decide to Commercialise these Relevant Products in that Relevant Country after the Effective Date and during the Commitment Period ("**Relaunch Product(s)**"), the Reduced Net Price to be applied to a Relaunch Product shall not be higher than the Reduced Net Price in Table I for the same Relevant Product and the same pack size in another Relevant Country where that Relevant Product had the same or closest comparable volume of sales in the most recent closed Financial Year to the volume of sales of the Relaunch Product during the last full Financial Year prior to the cessation of its previous period of Commercialisation.
- 12) For those Relevant Products never previously Commercialised by Aspen in that Relevant Country ("**Launch Product(s)**"), the volume amount for purposes of establishing the same or closest comparable volume of sales in the most recent Financial Year pursuant to paragraph 11) above, shall be the volume included in submissions to Regulatory Authorities, where so made, in the absence of which, the forecasted volume included in Aspen's final internal document including a forecasted volume (i.e., the Product Launch Request Form, as currently named by Aspen) that formed the basis for its decision to launch the Launch Product, and agreed by the relevant Regulatory Authority, or not objected to by the Regulatory Authority within sixty (60) days, following submission of the volume forecast to the Regulatory Authority. Such submission shall also advise the Regulatory Authority of the relevance of the volume forecast for the purposes of determining the Reduced Net Price to be applied.
- 13) For Relevant Products Commercialised in a Relevant Country between June 2019 and the Effective Date, the volume amount for purposes of establishing the same or closest comparable volume of sales in the most recent Financial Year pursuant to paragraphs 11) and 12) above, shall be established by extrapolating the available volume data to full year data.
- 14) In case of the launch of an entirely new pack size compared to those set out in Table I after the Effective Date and during the Commitment Period not previously commercialised in the Relevant Country, the Reduced Net Price of the new pack size shall be calculated by applying the Reduced Net Price of the same pack size in another Relevant Country where that Relevant Product had the same or closest comparable volume of sales in the most recent closed Financial Year to the forecasted volume included in Aspen's final Product Launch Request Form that formed the basis for its decision to launch the modified pack size, under the supervision of the Trustee. In case there is no such Relevant Country, the Reduced Net Price in relation to the new pack size shall be calculated proportionally per unit by reference to the next largest pack size. For the avoidance of doubt, this paragraph 14) is without prejudice to Aspen's rights under paragraph 46).

Supply commitments

- 15) For the Supply Commitment Period, subject to any limitations that may result from a) Events of Force Majeure, b) compliance with applicable laws, and c) any decision by a

Regulatory Authority, and which may apply only for the duration of the effects of such events in the Supply Commitment Period, Aspen commits to:

- i) maintain the registration of the marketing authorisations that it currently holds for the Relevant Products in the Relevant Countries, and
 - ii) continue to Commercialise the Relevant Products where they are so Commercialised on the Effective Date or any time thereafter during the Supply Commitment Period, on the basis of a market authorisation and/or through Foreign Pack supply pursuant to and in accordance with applicable local laws and in a manner no more cumbersome for the purchasers than as at the Effective Date. Aspen will ensure appropriate and continued supplies so that the needs in the Relevant Countries are covered.
- 16) For the Supplementary Supply Commitment Period, subject to any limitations that may result from a) Events of Force Majeure, b) compliance with applicable laws, and c) any decision by a Regulatory Authority, and which may apply only for the duration of the effects of such events in the Supplementary Supply Commitment Period, Aspen commits to continue to Commercialise in accordance with paragraph 15) ii); however, during the Supplementary Supply Commitment Period Aspen may decide to discontinue Commercialising a Relevant Product in a Relevant Country in accordance with requirements of applicable laws and provided that Aspen:
- i) notifies the relevant Regulatory Authority of its intention to discontinue Commercialising a Relevant Product in a Relevant Country at least eighteen (18) months before this discontinuation is to take effect; and
 - ii) offers its marketing authorisation for sale at least one (1) year before discontinuing to Commercialise a Relevant Product in a Relevant Country. Regarding the sale, Aspen commits to ensure that the marketing authorisation and any related dossiers, information or records are offered for sale to a third party on terms determined by Aspen acting in good faith. Aspen also commits to undertake best efforts to support the transfer of the supply arrangement for the relevant API to the acquirer. If the sale of one or more of the marketing authorisations of the Relevant Products does not occur within a period of six (6) months of Aspen offering the relevant marketing authorisation for sale, Aspen will offer to sell the marketing authorisation(s) concerned at no minimum price. As long as Aspen has not sold and effectively transferred its marketing authorisation, Aspen commits to maintain, during the Commitment Period, the registration of its marketing authorisation for as long as possible under applicable laws.
- 17) Aspen will not withdraw the marketing authorisation for any Relevant Product in any Relevant Country prior to the Entry Into Force.

Non-circumvention

- 18) Aspen shall not circumvent or attempt to circumvent the Commitments. In particular, Aspen shall not circumvent the Commitments by selling, assigning or otherwise transferring any part of its business relating to the supply of Relevant Products, other than in accordance with paragraph 16) above, or with the Commission's consent, such consent

not to be unreasonably withheld or delayed. Aspen will also refrain as of the Effective Date, from practices which have the object or effect of:

- i) increasing the price of any of the Relevant Products in any Relevant Country above the levels identified in the Commitments; or
- ii) reducing the number of tablets or vials of the Relevant Products Commercialised in any Relevant Country, unless Aspen can show that it ensures appropriate and continued supplies meeting the needs in the Relevant Countries. For the avoidance of doubt, nothing in this paragraph 18) shall prevent Aspen selling the Relevant Products in alternative pack sizes;
- iii) replacing any of the Relevant Products by withdrawing any of the Relevant Products while at the same time launching a new dose form containing the same API and registered for the treatment of the same indications as the replaced Products;
- iv) causing the marketing authorisations of the Relevant Products in the Relevant Countries to be withdrawn, revoked, suspended or modified to reduce existing indications.

Section C: Trustee

I. Appointment procedure

- 19) Aspen shall appoint a Trustee to carry out the functions specified in these Commitments.
- 20) The Trustee shall:
 - i) at the time of appointment, be independent of Aspen and of any competitor or customer of Aspen (and any other undertaking directly or indirectly controlled by or affiliated with any competitor or customer of Aspen);
 - ii) possess the necessary qualifications to carry out its mandate, for example have sufficient relevant experience as an investment banker or consultant or auditor or accountant; and
 - iii) neither have nor become exposed to a Conflict of Interest.
- 21) The Trustee shall be remunerated by Aspen in a way that does not impede the independent and effective fulfilment of its mandate.

Proposal by Aspen

- 22) No later than fourteen (14) days after the Entry Into Force, Aspen shall submit the name or names of one or more natural or legal persons whom Aspen proposes to appoint as the Trustee to the Commission for approval. The proposal shall contain sufficient information for the Commission to verify that the person or persons proposed as Trustee fulfil the requirements set out in paragraph 20) and shall include:

- i) the full terms of the proposed mandate, which shall include all provisions necessary to enable the Trustee to fulfil its duties under these Commitments; and
- ii) the outline of a work plan which describes how the Trustee intends to carry out the mandate.

Approval or rejection by the Commission

- 23) The Commission shall have the discretion to approve or reject the proposed Trustee(s) and to approve the proposed mandate subject to any modifications it deems necessary for the Trustee to fulfil its obligations. If only one name is approved, Aspen shall appoint or cause to be appointed the person or persons concerned as Trustee, in accordance with the mandate approved by the Commission. If more than one name is approved, Aspen shall be free to choose the Trustee to be appointed from among the names approved. The Trustee shall be appointed within one week of the Commission's approval, in accordance with the mandate approved by the Commission.

New proposal by Aspen

- 24) If all the proposed Trustees are rejected, Aspen shall submit the names of at least two more natural or legal persons within one week of being informed of the rejection in accordance with paragraphs 20) and 23).

Trustee nominated by the Commission

- 25) If all further proposed Trustees are rejected by the Commission, the Commission shall nominate a Trustee, whom Aspen shall appoint, or cause to be appointed, in accordance with a trustee mandate approved by the Commission.

II. Functions and obligations of the Trustee

- 26) The Trustee shall assume its duties specified in the Commitments to ensure Aspen's compliance with the Commitments. The Commission may, on its own initiative or at the request of the Trustee or Aspen, give any orders or instructions to the Trustee in order to ensure compliance with the Commitments. Aspen may not give instructions to the Trustee.
- 27) The Trustee shall propose within one (1) month of its appointment to the Commission a detailed work plan describing how it intends to monitor compliance with the obligations and conditions attached to the Commitment Decision.
- 28) As regards Aspen's obligations set out under paragraphs 6) to 14) "Price Commitments" as well as under paragraphs 15) to 17) "Supply Commitments", the Trustee shall:
 - i) monitor in particular the implementation of Aspen's Commitments regarding (i) the Net Price Reduction (Section B.1); (ii) the Transitory Rebate and Co-payment Rebate (Section B.2), including the obligations set out in Appendix 1, and (iii) the Commercialisation or re-commercialisation of new Relevant Products and/or new pack sizes (Section B.3);

- ii) monitor (i) Aspen's compliance during the Supply Commitment Period in accordance with paragraph 15) and (ii) Aspen's compliance during the Supplemental Supply Commitment Period in accordance with paragraph 16).
- 29) The Trustee shall in particular:
- i) propose to Aspen such measures as the Trustee considers necessary to ensure Aspen's compliance with the Commitments and the Trustee shall propose necessary measures to the Commission in the event that Aspen does not comply with the Trustee's proposal within the timeframe set by the Trustee;
 - ii) act as a contact point for any requests by third parties, including Regulatory Authorities and Appropriate Beneficiaries, in relation to the Commitments;
 - iii) within one hundred twenty (120) days from the date of the appointment, provide the Commission (sending Aspen a non-confidential copy at the same time):
 - a report of any issues or problems which may have risen in the execution of the Trustee's obligations; and
 - of any issues of non-compliance by Aspen with the Commitments.
 - iv) verify and confirm the calculations of the Transitory Rebate and Co-payment Rebate, based on the principles set out in these Commitments, before they are communicated to the Appropriate Beneficiaries and make itself available to explain the principles and methodology underlying the calculations to the Appropriate Beneficiaries;
 - v) verify before publication whether the information and notices to be sent to patients, doctors (including oncologists/haematologists) and pharmacists comply with the requirements laid down in paragraph 9) v);
 - vi) provide to the Commission (sending Aspen a non-confidential copy at the same time) a bi-monthly status report regarding the implementation of the Net Price Reductions and the payment of the Transitory Rebate and Co-payment Rebate pursuant to paragraph 9) until the total amount of the Transitory Rebate for each Relevant Country has been paid;
 - vii) without undue delay, inform the Commission about the last reminder to an Appropriate Beneficiary sent ten (10) days before the end of a given period pursuant to paragraph 9) ii) as well as the notifications to a Regulatory Authority pursuant to paragraph 9) iii);
 - viii) within five (5) working days as of the notification to a Regulatory Authority pursuant to paragraph 9) iii), provide the Commission (sending Aspen a non-confidential copy at the same time) a report covering Aspen's compliance with the obligations in paragraph 9) iii); inform the Commission without undue delay of Aspen's intention to cease the sale of any Relevant Product in any Relevant Country;

- ix) verify and confirm that it has not been possible to pay all or part of a Transitory Rebate to an Appropriate Beneficiary within the time-limit foreseen in paragraph 9) ii);
 - x) if applicable, provide to the Commission (sending Aspen a non-confidential copy at the same time) a report establishing that the payment of the Transitory Rebate and Co-payment Rebate pursuant to paragraphs 9) i to vi) has not been fully made, ten (10) working days prior to Aspen's payment of the remaining amount of the Transitory Rebate and Co-payment Rebate to the Residual Fall-back Recipient;
 - xi) within ninety (90) days from the end of each Financial Year (with effect from the Financial Year ending 30 June 2021) provide the Commission (sending Aspen a non-confidential copy at the same time) a written report covering the Trustee's fulfilment of its obligations and Aspen's compliance with the Commitments. The reports shall cover in particular the following topics:
 - (1) any issues or problems which have arisen in the execution of the obligations as Trustee;
 - (2) any issues of non-compliance by Aspen with the Commitments;
 - (3) review and assessment of the progress of the implementation of the Reduced Net Prices;
 - (4) the Gross Sales, the Net Sales and the volume of sales of the Relevant Products in the Relevant Countries;
 - (5) the sale of a marketing authorisation of a Relevant Product in a Relevant Country; and
 - (6) a proposal for a detailed work plan described at point (i) above for the then current Financial Year.
- 30) At any time, the Trustee will provide to the Commission, at its request (or on the Trustee's own initiative), a written or oral report on matters falling within the Trustee's mandate. In particular, the Trustee shall promptly report in writing to the Commission (sending Aspen a non-confidential version at the same time) if it concludes on reasonable grounds that Aspen is failing to comply with these Commitments. The Trustee shall inform Aspen promptly of the content of any oral reports to the Commission.

III. Duties and obligations of Aspen

- 31) Aspen shall provide and shall cause its advisors to provide the Trustee with all such co-operation, assistance and information as the Trustee may reasonably require to perform the mandate. The Trustee shall have full and complete access to:
- i) any of Aspen's books, records, documents, management or other personnel, facilities, sites and technical information, if and as necessary for fulfilling the mandate;

- ii) all correspondence with the Regulatory Authorities and Appropriate Beneficiaries covered by these Commitments, if and as necessary for fulfilling the mandate;
 - iii) all information on List Price, Net Price and, where relevant, Gross Price of the Relevant Products in the Relevant Countries, if and as necessary for fulfilling the mandate; and
 - iv) in the case of a reasoned request for review of the Reduced Net Prices, all calculations and underlying data necessary to calculate the EBITDA Margin in line with Appendix 2 of the Commitments.
- 32) All confidential information is provided by Aspen to the Trustee subject to due respect by the Trustee of the confidentiality of such information.
- 33) On reasonable request and notice, Aspen shall make available to the Trustee one or more offices on their premises. Aspen shall be available for meetings in order to provide the Trustee with all information necessary for the performance of the mandate.
- 34) Aspen will inform the Trustee of the full set of necessary steps to inform patients of the Co-payment Rebate, consult the Trustee on its communications to patients, doctors (including oncologists/haematologists) and pharmacists and consult with the Trustee before transferring any remaining balance of the Co-payment Rebate, as may exist, to the specific Fall-back Recipient identified in Appendix 1.
- 35) Aspen shall indemnify the Trustee and its employees and agents, as well as its advisors, and hold each of them harmless against, and hereby agrees that they shall have no liability to Aspen for, any liabilities arising out of the performance of the Trustee of the mandate, except to the extent that such liabilities result from the willful default, recklessness, gross negligence or bad faith of the Trustee, its employees, agents or advisors.
- 36) At the expense of Aspen, the Trustee may appoint advisors (in particular for corporate finance or legal advice), subject to Aspen's prior written approval (such approval not to be unreasonably withheld or delayed) if the Trustee considers the appointment of such advisors necessary or appropriate for the performance of the mandate, provided that any fees and other expenses incurred by the Trustee are reasonable. Should Aspen refuse to approve the advisors proposed by the Trustee the Commission may approve the appointment of such advisors instead, after having heard Aspen. Aspen is not entitled to issue instructions to the advisors. Such additional advisors must not have any conflict of interest with Aspen.
- 37) Aspen agrees that the Commission may share any confidential information which is proprietary to Aspen with the Trustee. The Trustee shall not disclose such information and the principles contained in Article 17(1) and (2) of the Merger Regulation and Article 28 of Regulation No. 1/2003 apply *mutatis mutandis*.
- 38) Aspen agrees that the contact details of the Trustee are published on the website of the Commission's Directorate-General for Competition and they shall inform interested third parties of the identity and the tasks of the Trustee.

- 39) Without prejudice to the Commission's investigative powers set out in Regulation 1/2003, for the Commitment Period, the Commission may request all information from Aspen that is reasonably necessary to monitor the effective implementation of these Commitments.

IV. Replacement, discharge and reappointment of the Trustee

- 40) If the Trustee ceases to perform its functions under the Commitments, ceases to perform its functions under the mandate, acts in breach of the mandate or for any other good cause, including the exposure of the Trustee to a Conflict of Interest, which the Trustee shall disclose to Aspen and to the Commission without delay:
- i) the Commission may, after hearing the Trustee, require Aspen to replace the Trustee; or
 - ii) Aspen may, with the prior approval of the Commission, replace the Trustee.
- 41) If the Trustee is discharged according to paragraph 40), the Trustee may be required to continue its mandate until a new Trustee is in place to whom the Trustee has effected a full hand over of all relevant information to carry out the mandate. The new Trustee shall be appointed in accordance with the procedure referred to in paragraphs 19) to 25) (inclusive).
- 42) Unless removed in accordance with paragraph 40), the Trustee shall cease to act as Trustee only after the Commission has discharged it from the mandate after all the Commitments with which the Trustee has been entrusted have been implemented. However, the Commission may at any time require the reappointment of the Trustee if it subsequently appears that the relevant remedies might not have been fully and properly implemented.

Section D: Review clause and Force Majeure

- 43) Pursuant to Article 9.2(a) of Regulation 1/2003, the Commission may, upon request or on its own initiative, reopen the proceedings where there has been a material change in any of the facts on which the Commitment Decision was based.
- 44) Without prejudice to Article 9.2(a) of Regulation 1/2003, the Commission may extend the time periods foreseen for the implementation of the Commitments in response to a reasoned request from Aspen or, in appropriate cases, on its own initiative. Where Aspen requests an extension of a time period, it shall submit a reasoned request to the Commission no later than thirty (30) days before the expiry of that period, showing good cause. This request shall be accompanied by a report from the Trustee, who shall, at the same time send a non-confidential copy of the report to Aspen.
- 45) Without prejudice to Article 9.2(a) of Regulation 1/2003, in case of an Event of Force Majeure, Aspen will submit to the Commission evidence demonstrating that event, substantiate how Aspen has fully exercised due care as required, and demonstrate that the event has an insurmountable impact on Aspen's ability to comply with its obligation to supply under the Commitments. To the extent it is confirmed by the Commission that Aspen is partially or entirely unable to comply with the obligation to supply under the Commitments due to an Event of Force Majeure, Aspen will be relieved of that obligation for the period that the inability to comply exists.

- 46) Without prejudice to Article 9.2(a) of Regulation 1/2003, Aspen may submit to the Commission one or more reasoned requests during or after the fifth year from the Effective Date to consider a one-time revision of the Reduced Net Prices set out in paragraph 6). The reasoned request(s) must be based on a significant change (i.e. above 20%) in Aspen's aggregated Direct Costs relating to all of the Relevant Products and all of the Relevant Countries. If the preceding condition is met, the Commission will assess Aspen's request(s) for the revision of the Reduced Net Prices in line with the assessment of profitability laid down in the Preliminary Assessment and with the assessment of cost allocation set out in Appendix 2 of the Commitments, subject to any adjustments to the assessment of cost allocation that may be required to reflect any subsequent changes in the reporting or accounting practices of Aspen at the time of the request(s). A possible one-time revision of the Reduced Net Prices set out in paragraph 6), if approved by the Commission, would apply without retroactive effect, and any price increases by Aspen would need to be implemented in full respect of, and subject to, applicable laws and rules of each Relevant Country concerned.
- 47) Reasoned requests pursuant to paragraph 46) shall be accompanied by a report from the Trustee assessing the alleged cost change and the requested revision, who shall, at the same time send a non-confidential copy of the report to Aspen.



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duly authorised for and on behalf of Aspen Pharmacare Holdings Limited and on behalf of its wholly owned subsidiary Aspen Pharma Ireland Limited

Stephen Saad

Group Chief Executive

List of Appendices

Appendix	Title	Description
Appendix 1	Payment of the Transitory Rebate and Co-payment Rebate and Appropriate Beneficiaries	Information on the payment of the Transitory Rebate and Co-payment Rebate to Appropriate Beneficiaries and/or Fall-back Recipients per Relevant Country
Appendix 2	Identification and allocation of indirect costs	A description of the application of the method in allocating Aspen's Indirect Costs to the Relevant Products in Aspen's FY2019 for the purposes of application of the Commitments
Appendix 3	Gross and List Prices for Relevant Products with List Prices Commercialised in FY2019	Relevant Products with List Prices Commercialised in FY2019 and reduced Gross and List Prices to achieve the Reduced Net Prices
Appendix 4	Regulatory Authorities	A list of Regulatory Authorities per Relevant Country before which Aspen should submit its pricing applications
Appendix 5	Gross Prices for Relevant Products without List Prices Commercialised in FY2019	Relevant Products without List Prices Commercialised in FY2019, and reduced and Gross Prices to achieve the Reduced Net Prices
Appendix 6	Prices for Relevant Products Commercialised or re-Commercialised since 1 July 2019 (section B.3 of the Commitments)	Relevant Products Commercialised or re-Commercialised since 1 July 2019 (section B.3 of the Commitments) and reduced Gross and List Prices to achieve the Reduced Net Prices

Case AT.40394 – Aspen

Appendix 1

Case AT.40394 – Aspen

Appendix 1 – Payment of the Transitory Rebate and Co-payment Rebate and Appropriate Beneficiaries

- 1) This Appendix forms an integral part of Aspen's Commitments and governs the implementation of the Transitory Rebate payments pursuant to paragraph 9) of the Commitments.¹
- 2) To ensure that Aspen, as of the Effective Date (1 October 2019), charges ultimately no higher Net Prices than the Reduced Net Prices, Aspen will pay a Transitory Rebate to one or more Appropriate Beneficiaries. The Transitory Rebate shall be calculated by Aspen based on the principles set out in paragraph 9) of the Commitments. In particular:
 - i) The Transitory Rebate will be calculated for the Transitory Period, being the time period between the Effective Date and the Implementation Date. The Implementation Date refers to the date upon which the Reduced Net Prices enter into effect either through selling at reduced Gross Prices, or at reduced prices following an official reduction of List Prices, as appropriate for each Product in the Relevant Country concerned.
 - ii) The calculation of the Transitory Rebate is based on Aspen's *sales* in each Relevant Country. For the avoidance of doubt, the calculation of the Transitory Rebate amount is therefore not based on the value of purchases or reimbursement by a given Appropriate Beneficiary, but rather Aspen's realised sales revenues.² Further, for the avoidance of doubt, in the case of Foreign Pack Sales, the Transitory Rebate shall thus be accounted for and included by Aspen in the calculation of the Transitory Rebate in the Relevant Country or Countries where Aspen placed it on the market and generated revenues. In contrast, Relevant Products purchased by parallel traders are accounted for in the country where Aspen placed them for the first time on the market and not in the country where a parallel trader sells the product (i.e. the final destination of the parallel import).
- 3) This Appendix 1 identifies the Appropriate Beneficiaries and Fall-back Recipients of the Transitory Rebate and, if there is more than one Appropriate Beneficiary in a given Relevant Country, the methodology for the allocation within each Relevant Country of the amount(s) of the Transitory Rebate.

Appropriate Beneficiaries

- 4) The tables below identify for each Relevant Country the Appropriate Beneficiary or Beneficiaries that will receive a Transitory Rebate payment. Where Aspen has identified more than one Appropriate Beneficiary, the tables identify how Aspen will allocate the

¹ Unless otherwise specified, capitalised terms shall have the meaning given in the Definitions of the Commitments.

² The amount of the Transitory Rebate and reimbursement amounts are not the same, because reimbursement amounts are based on prices that include also 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.

Transitory Rebate to the Appropriate Beneficiaries within each Relevant Country (referred to below as “**Methodology**”). Unless otherwise indicated, in the absence of available data to support the calculation of the allocation, the allocation of the Transitory Rebate as between different Appropriate Beneficiaries will be based on the following assumptions:

- i) each Appropriate Beneficiary (e.g., fund/insurance/region) provides coverage for oncology treatment;
 - ii) each Appropriate Beneficiary has the same per capita incidence of relevant types of cancer.
- 5) In the event individual patients had to pay some of the purchase price for the Products based on national co-payment obligations, Aspen will estimate the Co-payment Rebate being the relevant amount of the Transitory Rebate in the Relevant Country that will be allocated to those patients based on sales data and data from the relevant national health insurance funds, as appropriate.
 - 6) Immediately after the Entry Into Force, i.e., the date the Commitment Decision is notified to Aspen, Aspen will write to each Appropriate Beneficiary informing it that it is entitled to a Transitory Rebate and informing it of the estimated amount of the Transitory Rebate and how it will be determined.
 - 7) Immediately after the Implementation Date, Aspen will write to each Appropriate Beneficiary informing the latter of the amount of the Transitory Rebate as calculated by Aspen in accordance with paragraph 9) of the Commitments and this Appendix 1. Aspen will pay the Transitory Rebate within ninety (90) days after it has informed the Appropriate Beneficiary about the amount of the Transitory Rebate. The above deadline can be extended by sixty (60) additional days subject to an extension request submitted by the Appropriate Beneficiary within the original ninety (90) day period. To the extent that Aspen does not receive instructions from the Appropriate Beneficiary for payment of the Transitory Rebates, it shall send written reminders to the Appropriate Beneficiary every thirty (30) days and a last written reminder ten (10) days before the end of the given period.
 - 8) For the payment of the Co-payment Rebate, Aspen will take appropriate steps to effectively inform the patients who made a co-payment during the Transitory Period and will only consider claims received within eighteen (18) months after having taken first steps to inform the patients. To the extent Aspen has not received claim(s) eighteen (18) months after having taken first steps to inform the patients, Aspen will transfer any balance of the Co-payment Rebate to the specific Fall-back Recipient identified in this Appendix 1. In the event that first steps have been taken before the Implementation Date and the Implementation Date is delayed, the period of eighteen (18) months will be prolonged accordingly to ensure that the patients will have a period of at least six (6) months from the Implementation Date to claim the Co-payment Rebate. Patients are entitled to claim a share of their Co-payment Rebate for a given period before the Implementation Date, without prejudice to claiming the remaining part of their Co-payment Rebate later.

Fall-back Recipients

- 9) In the event that an Appropriate Beneficiary has not provided necessary instructions for some or all of the payment of a Transitory Rebate or if it was for other reasons not possible to pay all or part of the Transitory Rebate to the Appropriate Beneficiary, within the time-limit foreseen in paragraph 9) ii) of the Commitments, Aspen will notify the Regulatory Authority in the Relevant Country.

- 10) If after thirty (30) days following that notification, Aspen still has not received any instructions for payment to the Appropriate Beneficiary and if the Regulatory Authority has also not nominated an alternative recipient, Aspen will transfer any non-paid parts of the Transitory Rebate to the Fall-back Recipient identified in this Appendix 1. If the Regulatory Authority has nominated an alternative recipient, Aspen will instead pay the Transitory Rebate to this alternative recipient.

Residual Fall-back Recipient

- 11) If the above mechanisms fail, the Commitments provide moreover for a Residual Fall-back Recipient which is relevant only in the unlikely event that any payment of the Transitory Rebate has not been fully made to the Appropriate Beneficiaries or to the Fall-back Recipients or to the alternative recipient pursuant to paragraph 9 i) to vi) of the Commitments. The Residual Fall-back Recipient is identified in Section 2 of this Appendix 1.

Section 1: Appropriate Beneficiaries

1. AUSTRIA	
Appropriate Beneficiary	Aspen will pay the Transitory Rebate to the following beneficiaries: for the Social Health Insurance Funds (SHIFs), the Umbrella Organisation of the Social Security Institution (UO-SSI) (Dachverband der Sozialversicherungsträger) (SV), and the Länder. See Table A.
Methodology	<p>As there are several entities in Austria, listed in Table 1 of this Appendix, ultimately paying or reimbursing the Products' purchase price, Aspen will pay the Transitory Rebate to the relevant entities based on the allocation set out below.</p> <p>Aspen will use the following methodology to allocate the Transitory Rebate:</p> <ol style="list-style-type: none"> 1. Aspen will pay 60% of the Transitory Rebate to the UO-SSI; the UO-SSI will further distribute the Transitory Rebate to the SHIFs. 2. Aspen will pay the remaining 40% of the Transitory Rebate to the Länder. Aspen will distribute the amount between the Länder based on the population key and will pay the Transitory Rebate to the different Länder based on instructions provided by Oö. Gesundheitsfonds, after consultation with the other Länder.
Fall-back Recipient	If it is not possible to pay some or all of the Transitory Rebate to any of the Appropriate Beneficiaries Aspen will, pursuant to paragraph 9) of the Commitments, pay any remainder amount to the following Fall-back Recipient: the Federal Health Agency (Bundesgesundheitsagentur).

2. BELGIUM	
Appropriate Beneficiary	Aspen will pay the Transitory Rebate to the Belgian federal government via the National Institute for Health and Disability Insurance (Belgische federale regering/ Gouvernement fédéral belge) (Rijksinstituut voor ziekte- en invaliditeitsverzekering (RIZIV) / (Institut national d'assurance maladie-invalidité (INAMI)).
Fall-back Recipient	If it is not possible to pay some or all of the Transitory Rebate to the Appropriate Beneficiary, and if the Regulatory Authority does not nominate an alternative recipient (as laid down in paragraph 9) of the Commitments), Aspen will, pursuant to paragraph 9) of the Commitments, pay any remainder amount to the following Fall-back Recipient: The Cancer Centre of Sciensano (Het Kankercentrum van Sciensano / Le Centre du Cancer de Sciensano).

3. BULGARIA	
Appropriate Beneficiary	Aspen will pay any Transitory Rebate in the form of a donation to the National Health Insurance Fund (NHIF) (Национална здравноосигурителна каса) (НЗОК).
Fall-back Recipient	If it is not possible to pay some or all of the Transitory Rebate to the Appropriate Beneficiary, and if the Regulatory Authority does not nominate an alternative recipient (as laid down in paragraph 9) of the Commitments), Aspen will, pursuant to paragraph 9) of the Commitments, pay any remainder amount to the following Fall-back Recipient: Ministry of Health (Министерство на здравеопазването).

4. CZECH REPUBLIC	
Appropriate Beneficiary	Aspen will pay the Transitory Rebate to the seven Public Health Insurance Funds (Fondy veřejného zdravotního pojištění) (PHIFs) and individual patients who incurred a co-payment. See Table A below.
Methodology	<p>As there are several entities in the Czech Republic ultimately paying or reimbursing the Products' purchase price, as well as individual patients that might have paid some of the purchase price for the Products through co-payments, Aspen will pay the Transitory Rebate to the relevant entities/individuals based on the allocation set out below:</p> <ul style="list-style-type: none"> A. Firstly, Aspen will calculate the value of the total Transitory Rebate based on Aspen's internal and Aspen's Agents' sales, being the difference between Aspen's existing Net Sales during the Transitory Period less its theoretical Net Sales had the same volumes been sold at the Reduced Net Prices, i.e., in accordance with paragraph 9) of the Commitments; and B. Secondly, Aspen will calculate the Co-payment Rebate attributable to individual patients who made a co-payment based on the difference between the co-payment amount per pack under the existing prices, if any, and the theoretical co-payment amount based on the reduced List Prices and the ratio between the current applicable co-payment level and the existing Pharmacy Selling Prices (i.e., the difference between current reimbursement prices and Pharmacy Selling Prices). The total Co-payment Rebate will be equal to the Co-payment Rebate per pack multiplied by the number of packs sold by Aspen during the Transitory Period, i.e., between 1 October 2019 and the Implementation Date (i.e., the date the reduction of the List Prices becomes effective). <p>1. Payment to individual patients</p> <ul style="list-style-type: none"> i. Aspen will take appropriate measures to inform patients about the Co-payment Rebate, within two (2) months from the Entry into Force of the Commitments, subject to applicable laws and regulations, as follows. ii. Within two (2) months from the Entry into Force of the Commitments, in order to notify patients that may have made co-payments Aspen will: <ul style="list-style-type: none"> a. ask to publish a notice on the SUKL website, or the websites of oncology/haematology societies or PHIFs. In accordance with the notice, any patients that were required to make co-payments on the Products between 1 October 2019 and the Implementation Date would be entitled to a rebate from the Co-payment Transitory Rebate as calculated in B above; b. contact via email doctors, in particular oncologists/haematologists, and pharmacists, and request that they inform the patients that made co-payments during the mentioned period that they would be entitled to a Co-payment Rebate as calculated in B above;

4. CZECH REPUBLIC

- c. make available notices/flyers with the relevant information to the doctors (including oncologists/haematologists) and pharmacists, so as to publish in their rooms and/or hand out to the patients to whom they are prescribing and dispensing the Relevant Products.
 - iii. The notice/flyers referred to in 1.ii. will contain:
 - a. clear information on the reasons why the patients can claim part of the Co-payment Rebate;
 - b. the period for which they are entitled to the Co-payment Rebate;
 - c. the amount of the Co-payment Rebate per pack for those who made a co-payment;
 - d. information on how the patients can claim the Co-payment Rebate,
 - e. information that proof of co-payment provided by pharmacists or by PHIFs in the form of electronic healthcare record are as well accepted as a proof of purchasing; and
 - f. the date by which they can claim the Co-payment Rebate.
 - iv. Aspen's communications shall comply with applicable national and EU rules on advertising of pharmaceutical prescription medicines.
 - v. Individual patients claiming a rebate should substantiate the claims with proof of purchasing the Products, for example proof of co-payment provided by pharmacists or by PHIFs in the form of electronic healthcare record.
 - vi. Individual patients who made a co-payment will have a period of eighteen (18) months to claim a Co-Payment Rebate. This period will start running from the date Aspen has first taken steps to inform the patients. In the event that first steps have been taken before the Implementation Date and the Implementation Date is delayed, the period of eighteen (18) months will be prolonged accordingly to ensure that the patients will have a period of at least six (6) months from the Implementation Date to claim the Co-Payment Rebate. Patients are entitled to claim a share of their Co-Payment Rebate for a given period before the Implementation Date, without prejudice to claiming the remaining part of their Co-payment Rebate later.
- 2. Payment to PHIFs**
 - i. Aspen will calculate and allocate the Transitory Rebate to be paid to the PHIFs as follows immediately after the Implementation Date:
 - a. In order to allocate the Transitory Rebate among the PHIFs, Aspen will contact PHIFs or the "National registry of reimbursed services" to obtain reimbursement data to allocate the appropriate amounts;
 - b. In the absence of more suitable data from the above sources, Aspen will pay the Transitory Rebate to the PHIFs in proportion to the respective number of patients of each PHIF; and

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	<p>c. As applicable, from the total value of the Transitory Rebate, calculated as per A. above, Aspen will deduct the value of the total Co-payment Transitory Rebate in accordance with B. above. The remaining balance of the Transitory Rebate will be the amount payable to the PHIFs.</p>
Fall-back recipient	<p>For the seven PHIFs: if it is not possible to pay some or all of the Transitory Rebate to the Appropriate Beneficiary, and if the Regulatory Authority does not nominate an alternative recipient (as laid down in paragraph 9) of the Commitments), Aspen will, pursuant to paragraph 9) of the Commitments, pay any remainder amount to the following Fall-back Recipient: PHIF – “redistribution account” (“redistribuční účet”).</p> <p>For individual patients who incurred a co-payment cost: after the expiry of eighteen (18) months from the date of the notification to patients, any unclaimed Co-payment Transitory Rebates will be allocated between the PHIFs in proportion to their reimbursement data.</p>

5. DENMARK	
Appropriate Beneficiary	Aspen will pay the Transitory Rebate to the five (5) Regions (Regioner) via Amgros. See Table A below.
Methodology	<p>As there are several entities in Denmark ultimately paying or reimbursing the Products' purchase price, Aspen will pay the Transitory Rebate to the relevant entities based on the allocation set out below.</p> <p>Aspen will pay the Transitory Rebate centrally to Amgros who will channel the money to the ultimate payer in the Regions.</p> <p>In order to determine the share of the money between the different Regions, Aspen will provide the following information to Amgros:</p> <ol style="list-style-type: none"> 1. Total amount of the Transitory Rebate; 2. The Products (Alkeran tablets; Leukeran, Lanvis, Myleran and Purinethol); and 3. The Transitory Period.
Fall-back Recipient	If it is not possible to pay some or all of the Transitory Rebate to the Appropriate Beneficiary, and if the Regulatory Authority does not nominate an alternative recipient (as laid down in paragraph 9) of the Commitments), Aspen will, pursuant to paragraph 9) of the Commitments, pay any remainder amount to the following Fall-back Recipient: Danish Comprehensive Cancer Centre (DCCC).

6. ESTONIA	
Appropriate Beneficiary	Aspen will pay the Transitory Rebate to the Estonian Health Insurance fund (EHIF) (Eesti Haigekassa) on the basis of an invoice issued by EHIF to Aspen.
Fall-back Recipient	If it is not possible to pay some or all of the Transitory Rebate to the Appropriate Beneficiary, and if the Regulatory Authority does not nominate an alternative recipient (as laid down in paragraph 9) of the Commitments), Aspen will, pursuant to paragraph 9) of the Commitments, pay any remainder amount to the following Fall-back Recipient: North Estonia Medical Centre (Põhja-Eesti Regionaalhaigla).

7. FINLAND	
Appropriate Beneficiary	Aspen will pay the Transitory Rebate to the twenty-one (21) Hospital districts (Sairaanhoitopiiri) (for in-patient use) and to the Social Insurance Institution of Finland's (Kansaneläkelaitos (KELA)) health insurance fund (for out-patient use). See Table A below.
Methodology	<p>As there are several entities in Finland ultimately paying and reimbursing the Products' purchase price, Aspen will pay the Transitory Rebate to the relevant entities based on the allocation set out below:</p> <ol style="list-style-type: none"> 1. Aspen will calculate the total value of the Transitory Rebate, and identify the proportion of the Transitory Rebate attributable to KELA on the one hand, and to the hospital districts, by region, on the other based on available Aspen's Agent and wholesaler data. 2. Aspen will use the combined sales per channel/Region to proportionately allocate the Transitory Rebates for any Foreign Pack import Products to the channels/Regions, to the extent that regional sales data is not available for a particular Product. 3. In cases where regions have combined together for the purposes of tenders or other purchases, Aspen will allocate the amount of the Transitory Rebate between the relevant Regions in proportion to their purchases outside of such combined purchases.
Fall-back Recipient	If it is not possible to pay some or all of the Transitory Rebate to the Appropriate Beneficiary, and if the Regulatory Authority does not nominate an alternative recipient (as laid down in paragraph 9) of the Commitments), Aspen will, pursuant to paragraph 9) of the Commitments, pay any remainder amount to the following Fall-back Recipient: Comprehensive Cancer Center Finland (FICAN) (Suomen Syöpäkeskus).

8. FRANCE	
Appropriate Beneficiary	Aspen will pay the Transitory Rebate to the Health Insurance System (Caisse nationale d'assurance maladie (CNAM) via l'Agence Centrale des Organismes de Securite Sociale (ACOSS)) after Aspen has received instructions for the details of the payment from the Comité économique des produits de santé (CEPS).
Fall-back Recipient	If it is not possible to pay some or all of the Transitory Rebate to the Appropriate Beneficiary, and if the Regulatory Authority does not nominate an alternative recipient (as laid down in paragraph 9) of the Commitments), Aspen will, pursuant to paragraph 9) of the Commitments, pay any remainder amount to the following Fall-back Recipient: French National Cancer Institute (Institut National Du Cancer).

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Appropriate Beneficiary	<p>Aspen will pay the Transitory Rebate to the following Appropriate Beneficiaries:</p> <ol style="list-style-type: none"> 1. For the GKV's (Gesetzliche Krankenversicherungen), the GKV-Spitzenverband; 2. For the PKV's (Private Krankenversicherungen), the Verband der Privaten Krankenversicherung (PKV-Verband); 3. Two (2) closed funds affiliated to the PKV-Verband; Krankenversorgung der Bundesbahnbeamten (KVB) and Postbeamtenkrankenkasse (PBEAKK) (the Closed Funds), which will be paid directly; 4. For the Beihilfe, the Krebsinformationsdienst (KID) of the Deutsche Krebsforschungszentrums (DKFZ), a public foundation funded by both the Federal Republic and the Länder; 5. Individual patients who made a co-payment. <p>See Table A below.</p>
Methodology	<p>As there are several entities in Germany ultimately paying or reimbursing the Products' purchase price, and individual patients who pay some of the purchase price for the Products through co-payments, Aspen will pay the Transitory Rebate to the relevant entities/individuals based on the allocation set out below.</p> <ol style="list-style-type: none"> 1. Firstly, Aspen will calculate the Co-payment Rebate applicable to individual patients who made a co-payment: <ol style="list-style-type: none"> i. The co-payment amount per pack under the existing prices will be compared to the theoretical co-payment amount under the Reduced Net Prices and the difference between the two will be the amount that will be paid, per pack, to the patients that are entitled to a co-payment related rebate. Also, this amount, multiplied by the number of packs sold by Aspen during the Transitory Period will be the total amount of the Co-payment Rebate applicable to co-payment claims. ii. Aspen will notify the patients who made a co-payment on the Products between 1 October 2019 and the Implementation Date (Implementation Date will be the date of the reduction of the List Prices) as follows. iii. Within two (2) months from the Entry into Force of the Commitments, in order to notify patients that may have made co-payments Aspen will: <ol style="list-style-type: none"> a) publish a notice on the Pharmazeutische Zeitung magazine as soon as possible after the Implementation Date and up to three times as permitted by Pharmazeutische Zeitung. The notice shall indicate that patients that were required to make co-payments on the

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	<p>Products between 1 October 2019 and the Implementation Date would be entitled to a rebate from the Transitory rebate as calculated in 1.i. above;</p> <p>b) as soon as possible after the Implementation Date send letters to oncologists/hematologists and pharmacists asking them to inform the patients that made co-payments during the mentioned period that they would be entitled to a Co-payment Rebate as calculated in 1. i. above;</p> <p>c) the communication under section iii. b) above shall include a flyer with the information set out in 1. iv. as well as details on how to obtain more flyers so as to hand out to the patients to whom they are prescribing and dispensing the Products.</p> <p>iv. The notice referred to in 1. iii. will contain:</p> <p>a) clear information on the reasons why the patients can claim a Co-payment Rebate;</p> <p>b) the period for which they are entitled to a Co-payment Rebate;</p> <p>c) the amount of the Co-payment Rebate per pack for those who made a co-payment;</p> <p>d) information on how the patients can claim the Co-payment Rebate, and</p> <p>e) the date by which they can claim the Co-payment Rebate.</p> <p>v. Aspen's communications shall comply with applicable national and EU rules on advertising of pharmaceutical prescription medicines.</p> <p>vi. The patients should substantiate the claim with a proof of purchasing; however, Aspen will also accept the proof of co-payment provided by pharmacists.</p> <p>vii. The individual patients who made a co-payment will have a period of eighteen (18) months to claim the Co-payment Rebate. This period will start running from the date Aspen has taken first steps to inform the patients. Should the Implementation Date be delayed, the period of eighteen (18) months will be prolonged accordingly to ensure that the patients will have a period of at least six (6) months from the Implementation Date to claim the Co-payment Rebate. Patients are entitled to claim a Co-payment Rebate for a given period before the Implementation Date, without prejudice to claiming the remaining part of their Co-payment Rebate later.</p>
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2. Secondly Aspen will calculate and allocate the Transitory Rebate to be paid to the GKV, PKV, the Closed Funds and Beihilfe:

- i. Aspen will calculate the value of the total Transitory Rebate based on Aspen's internal and Aspen's Agents' sales, being the difference between Aspen's existing Net Sales during the Transitory Period less its theoretical Net Sales had the same volumes been sold at the Reduced Net Prices;
- ii. From this value Aspen will deduct the value of the Co-payment Rebate applicable to patients who made co-payments calculated in terms of 1.i. above. The remaining balance of the Transitory Rebate will be paid to the GKV, PKV, the Closed Funds and Beihilfe.

Aspen will pay the Transitory Rebate on a per capita basis as follows :

- iii. Aspen will identify the average number of patients covered by GKV, PKV, Closed Funds in 2020. On the assumption that each fund within the GKV, PKV and Closed Funds provides coverage for oncology treatment, and that each fund has the same per capita incidence of relevant types of cancer, Aspen will allocate the Transitory Rebate pro rata based on average membership data for 2020. Aspen will determine the portion of the PKV membership and contributions that are funded by Beihilfe and thereby will determine that portion of the PKV Transitory Rebate attributable to Beihilfe.
- iv. Aspen will calculate the rebate allocation between the three (3) main categories (GKV, PKV and Beihilfe):
 - a) During 2020 a total of 104 GKV had an average aggregate number of persons covered of 73.41 million and 42 PKV (of which 35 provide comprehensive health insurance) an average aggregate of 8.73 million. In addition, the two closed funds covered 0.63 million. This gives a total of insured persons of 82.76 million.
 - b) The PKV-Verband has confirmed that in 2019 approximately 51% of all substitutive health insurance policyholders were eligible for aid (Beihilfe – available to civil servants and their family members without own income). In the event of illness, they are entitled to receive benefits from Beihilfe. The public employer then pays at least 50 percent of the treatment costs (70 percent for civil servants having at least two children; the same applies to spouses and pensioners. The Beihilfe rate for children is 80 percent). The remaining costs are covered by an aid plan of the private health insurance.
 - c) The share of private health insurance in the expenditure on benefits is 7% according to the ratio of statutory and

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	<p>privately insured persons after deducting the costs covered by the Beihilfe fund/payer. This is also the value currently laid down by the German legislature in several sections of the German Social Code that define the share of the PKV, cf. for example sec. 65e para. 1 sentence 2 SGB Book V (German Social Code) on the share of private health insurance in the costs of cancer counseling centers.</p> <p>d) On this basis, Aspen will allocate the Transitory Rebate, as calculated above, to be paid to the GKV's, PKV's, Beihilfe and Closed Funds is as follows:</p> <ul style="list-style-type: none"> o GKVs: 88.7% o PKVs: 7% o Beihilfe: 3.5% o Closed Funds: KVB: 0.3%, Postbeamte: 0.5%. <p>v. Aspen will pay the Transitory Rebates at an aggregate level to the following entities:</p> <ul style="list-style-type: none"> a) For the GKVs: the GKV-Spitzenverband b) For the PKVs: the PKV-Verband c) For the Closed Funds: to the two Closed Funds directly d) For the Beihilfe: the KID of the DKFZ <p>vi. Aspen will pay the Transitory Rebate to the above-mentioned entities. GKV-Spitzenverband and PKV-Verband will allocate and distribute the Transitory Rebate to the individual GKV and PKV funds, respectively.</p>
Fall-back Recipient	<p>For the GKVs and PKVs: If it is not possible to pay some or all of the Transitory Rebate to the Appropriate Beneficiary, and if the Regulatory Authority does not nominate an alternative recipient (as laid down in paragraph 9) of the Commitments), Aspen will, pursuant to paragraph 9) of the Commitments, pay any remainder amount to the following Fall-back Recipient: German Cancer Consortium (DKTK).</p> <p>For Beihilfe: If it is not possible to pay some or all of the Transitory Rebate to the Appropriate Beneficiary, and if the Regulatory Authority does not nominate an alternative recipient (as laid down in paragraph 9) of the Commitments), Aspen will, pursuant to paragraph 9) of the Commitments, pay any remainder amount to the following Fall-back Recipient: Georg Speyer Haus.</p> <p>For individual patients who incurred a co-payment cost: After the expiry of eighteen (18) months from the date of the notification to patients, any</p>

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	unclaimed Co-payment Rebates will be allocated to the German Cancer Consortium (DKTK).
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10. GREECE	
Appropriate Beneficiary	Aspen will pay the Transitory Rebate to the Pharmaceutical Research and Technology company (IFET) (Ινστιτούτο Φαρμακευτικής Έρευνας & Τεχνολογίας ΑΕ) (ΙΦΕΤ) via a credit note.
Fall-back Recipient	If it is not possible to pay some or all of the Transitory Rebate to the Appropriate Beneficiary, and if the Regulatory Authority does not nominate an alternative recipient (as laid down in paragraph 9) of the Commitments), Aspen will, pursuant to paragraph 9) of the Commitments, pay any remainder amount to the following Fall-back Recipient: the Common Health Insurance Fund (Εθνικός Οργανισμός Παροχής Υπηρεσιών Υγείας) (Ε.Ο.Π.Υ.Υ.).

11. HUNGARY	
Appropriate Beneficiary	Aspen will pay the Transitory Rebate to hospitals or clinics, as identified based on internal and wholesaler data, via credit notes.
Fall-back Recipient	If it is not possible to pay some or all of the Transitory Rebate to the Appropriate Beneficiary, and if the Regulatory Authority does not nominate an alternative recipient (as laid down in paragraph 9) of the Commitments), Aspen will, pursuant to paragraph 9) of the Commitments, pay any remainder amount to the following Fall-back Recipient: Dél-Pesti Centrumkórház - Országos Hematológiai És Infektológiai Intézet.

12. ICELAND	
Appropriate Beneficiary	Aspen will pay the Transitory Rebate to the Icelandic Health Insurance (NHS) (Sjúkratryggingar Íslands).
Fall-back Recipient	If it is not possible to pay some or all of the Transitory Rebate to the Appropriate Beneficiary, and if the Regulatory Authority does not nominate an alternative recipient (as laid down in paragraph 9) of the Commitments), Aspen will, pursuant to paragraph 9) of the Commitments, pay any remainder amount to the following Fall-back Recipient: Landspítali - The National University Hospital of Iceland (Føroyskt – Landspítali).

13. IRELAND	
Appropriate Beneficiary	Aspen will pay the Transitory Rebate to the Health Service Executive (HSE) (Feidhmeannacht na Seirbhíse Sláinte).
Fall-back Recipient	If it is not possible to pay some or all of the Transitory Rebate to the Appropriate Beneficiary, and if the Regulatory Authority does not nominate an alternative recipient (as laid down in paragraph 9) of the Commitments), Aspen will, pursuant to paragraph 9) of the Commitments, pay any remainder amount to the following Fall-back Recipient: Precision Oncology Ireland.

14. LATVIA	
Appropriate Beneficiary	Aspen will pay Transitory Rebate to the National Health Service (Nacionālais veselības dienests) (NVD).
Fall-back Recipient	If it is not possible to pay some or all of the Transitory Rebate to the Appropriate Beneficiary, and if the Regulatory Authority does not nominate an alternative recipient (as laid down in paragraph 9) of the Commitments), Aspen will, pursuant to paragraph 9) of the Commitments, pay any remainder amount to the following Fall-back Recipient: Riga East University Hospital/Latvian Oncology Centre (Rīgas Austrumu klīniskā universitātes slimnīca/Stacionārs Latvijas Onkoloģijas centrs).

15. LITHUANIA	
Appropriate Beneficiary	Aspen will pay the Transitory Rebate to the Compulsory Health Insurance Fund (Valstybinė Ligonių Kasa) (VLK).
Fall-back Recipient	If it is not possible to pay some or all of the Transitory Rebate to the Appropriate Beneficiary, and if the Regulatory Authority does not nominate an alternative recipient (as laid down in paragraph 9) of the Commitments), Aspen will, pursuant to paragraph 9) of the Commitments, pay any remainder amount to the following Fall-back Recipient: National Cancer Institute (Nacionalinis vėžio institutas).

16. MALTA	
Appropriate Beneficiary	Aspen will pay the Transitory Rebate to the Ministry for Health (Ministeru għas-Saħħa) via the Central Procurement and Supplies Unit (CPSU) Health Department - Ministry for Health (MfH).
Fall-back Recipient	If it is not possible to pay some or all of the Transitory Rebate to the Appropriate Beneficiary, and if the Regulatory Authority does not nominate an alternative recipient (as laid down in paragraph 9) of the Commitments), Aspen will, pursuant to paragraph 9) of the Commitments, pay any remainder amount to the following Fall-back Recipient: Sir Anthony Mamo Oncology Centre (Centru ta' l-Onkologija Sir Anthony Mamo).

17. NETHERLANDS	
Appropriate Beneficiary	Aspen will pay the Transitory Rebate to the twenty-four (24) Health Insurance Companies (Zorgverzekeraars). See Table A below.
Methodology	<p>As there are several entities in the Netherlands ultimately paying or reimbursing the Products' purchase price, Aspen will pay the Transitory Rebate to the relevant entities as set out below.</p> <ol style="list-style-type: none"> 1. Aspen will calculate the value of the Transitory Rebate per Product based on Aspen's Net Sales. 2. Aspen will pay the Transitory Rebate to Zorgverzekeraars Nederland (ZN), the umbrella organisation of health insurers. ZN will allocate to the twenty-four (24) Health Insurer Companies in proportion to their membership as a share of the insured population and distribute to each Health Insurer Company its part of the Transitory Rebate.
Fall-back Recipient	If it is not possible to pay some or all of the Transitory Rebate to the Appropriate Beneficiary, and if the Regulatory Authority does not nominate an alternative recipient (as laid down in paragraph 9) of the Commitments), Aspen will, pursuant to paragraph 9) of the Commitments, pay any remainder amount to the following Fall-back Recipient: the Netherlands Cancer Institute (Nederlands Kanker Instituut) (NKI).

18. NORWAY	
Appropriate Beneficiary	Aspen will pay the Transitory Rebate to the Regional Health Authorities (Regionalt helseforetak) (RHF). See Table A below.
Methodology	<p>As there are several entities in Norway ultimately paying or reimbursing the Products' purchase price, Aspen will pay the Transitory Rebate to the relevant entities based on the allocation set out below.</p> <ol style="list-style-type: none"> 1. Aspen will calculate the Transitory Rebate based Aspen's Net Sales data according to paragraph 9) of the Commitments. 2. Aspen will allocate the amount of the Transitory Rebate among the RHF's based on by Product and by Region data on sales data provided by the Norwegian Hospital Procurement Trust (Sykehusinnkj�p) for the same period, if available. Alternatively, Aspen will allocate the Transitory Rebate to the RHF's on the basis of available sales data from Aspen's Agents and/or wholesalers by Product and by Region. 3. Aspen will pay a part of the Transitory Rebate to each of the RHF's based on payment instructions to be provided by Sykehusinnkj�p.
Fall-back Recipient	If it is not possible to pay some or all of the Transitory Rebate to the Appropriate Beneficiary, and if the Regulatory Authority does not nominate an alternative recipient (as laid down in paragraph 9) of the Commitments), Aspen will, pursuant to paragraph 9) of the Commitments, pay any remainder amount to the following Fall-back Recipient: Institute for Cancer Research, Oslo University Hospitals (Institutt for Kreftforskning, Oslo Universitetssykehus).

19. POLAND	
Appropriate Beneficiary	Aspen will pay the Transitory Rebate to the National Health Fund in the form of a donation to the National Health Fund (Narodowy Fundusz Zdrowia) (NFZ).
Fall-back Recipient	If it is not possible to pay some or all of the Transitory Rebate to the Appropriate Beneficiary, and if the Regulatory Authority does not nominate an alternative recipient (as laid down in paragraph 9) of the Commitments), Aspen will, pursuant to paragraph 9) of the Commitments, pay any remainder amount to the following Fall-back Recipient: Maria Skłodowska-Curie National Research Institute Of Oncology (Narodowy Instytut Onkologii im. Marii Skłodowskiej-Curie – Państwowy Instytut Badawczy).

20. PORTUGAL	
Appropriate Beneficiary	Aspen will pay any Transitory Rebate to hospitals.
Methodology	<p>Aspen will pay any Transitory Rebate to the relevant hospitals based on the allocation set out below:</p> <ol style="list-style-type: none"> 1. Based on Aspen's internal and Aspen's Agents' sales data, Aspen will calculate the value of the Transitory Rebate per Product per customer. 2. Aspen will issue a credit note addressed to the hospital accompanied by an explanatory communication (either through its Agent or the relevant wholesaler(s)) for the amount as calculated above. 3. In the event that the hospital no longer acquires any products from Aspen (including products other than the Products), Aspen will arrange for a cash refund to the hospital.
Fall-back Recipient	If it is not possible to pay some or all of the Transitory Rebate to the Appropriate Beneficiary, and if the Regulatory Authority does not nominate an alternative recipient (as laid down in paragraph 9) of the Commitments), Aspen will, pursuant to paragraph 9) of the Commitments, pay any remainder amount to the following Fall-back Recipient: Central Administration of the Health System– (Administração Central do Sistema de Saúde, I.P.) (ACSS) through the issue of billing documents.

21. ROMANIA	
Appropriate Beneficiary	Aspen will pay the Transitory Rebate to the Romanian National Health Insurance House (NHIH) (Casa Națională de Asigurări de Sănătate) (CNAS).
Fall-back Recipient	If it is not possible to pay some or all of the Transitory Rebate to the Appropriate Beneficiary, and if the Regulatory Authority does not nominate an alternative recipient (as laid down in paragraph 9) of the Commitments), Aspen will, pursuant to paragraph 9) of the Commitments, pay any remainder amount to the following Fall-back Recipient: Oncology Institute „Prof. Dr I. Chiricuta” Cluj-Napoca.

22. SLOVAKIA	
Appropriate Beneficiary	Aspen will pay the Transitory Rebate to the three Public Health Insurance Funds (PHIFs) (Verejné zdravotné poisťovne). See Table A below.
Methodology	<p>As there are several entities ultimately paying or reimbursing the Products' purchase price, Aspen will pay the Transitory Rebate to the relevant entities based on the allocation set out below.</p> <ol style="list-style-type: none"> 1. Aspen will calculate the value of the Transitory Rebate based on paragraph 9) of the Commitments. 2. Aspen will allocate and pay the Transitory Rebate to the PHIFs in proportion to the PHIFs' membership as a share of the insured population based on available data. Aspen may also rely for allocation purposes on alternative data from the PHIFs, subject to having complete and consistent to data from all PHIFs.
Fall-back Recipient	If it is not possible to pay some or all of the Transitory Rebate to the Appropriate Beneficiary, and if the Regulatory Authority does not nominate an alternative recipient (as laid down in paragraph 9) of the Commitments), Aspen will, pursuant to paragraph 9) of the Commitments, pay any remainder amount to the following Fall-back Recipient: Cancer Research Institute of the Slovak Academy of Sciences (CRI SAS) (Ústav experimentálnej onkológie - Slovenská akadémia vied) (SAV).

23. SLOVENIA	
Appropriate Beneficiary	Aspen will pay the Transitory Rebate to the Health Insurance Institute of Slovenia (Zavod za zdravstveno zavarovanje Slovenije) by entering into an agreement involving a refund for overspend.
Fall-back Recipient	If it is not possible to pay some or all of the Transitory Rebate to the Appropriate Beneficiary, and if the Regulatory Authority does not nominate an alternative recipient (as laid down in paragraph 9) of the Commitments), Aspen will, pursuant to paragraph 9) of the Commitments, pay any remainder amount to the following Fall-back Recipient: Ljubljana Institute of Oncology (Onkološki inštitut Ljubljana).

24. SPAIN	
Appropriate Beneficiary	Aspen will pay the Transitory Rebate to the seventeen autonomous regions (Comunidades Autonomas) and (if applicable) two autonomous cities managed by the National Health Management Institute (Instituto Nacional de Gestión Sanitaria-INGESA), the private hospitals, private clinics and other private customers, and, if applicable, mutual benefit societies for national civil servants, i.e., MUFACE (General Administration), MUGEJU (Justice Administration) and ISFAS (Defense Administration), to the extent not covered in the payment of the Transitory Rebate to the private customers.
Methodology	<p>As there are several entities in Spain ultimately paying or reimbursing the Products' purchase price, Aspen will pay the Transitory Rebate to the relevant entities based on the allocation set out below.</p> <p>Aspen will allocate and pay the Transitory Rebate attributable to public hospital sales to the seventeen autonomous regions and (if applicable) to the two autonomous cities.</p> <p>As regards sales to private hospitals, clinics and other private customers, Aspen will pay the amount of Transitory Rebate via credit notes to the relevant customers, i.e. private hospitals, clinics and others, and, if applicable, mutual benefit societies for national civil servants, i.e., MUFACE (General Administration), MUGEJU (Justice Administration) and ISFAS (Defense Administration) to the extent not covered in the payment of the Transitory Rebate to the private customers.</p> <p>Aspen will calculate, allocate and pay the Transitory Rebate in accordance with the following methodology:</p> <ol style="list-style-type: none"> 1. Aspen will calculate the value of the Transitory Rebate based on paragraph 9) of the Commitments. 2. Aspen will identify the customers that purchased the Products based on Aspen's internal and Aspen's Agents' sales data as well as the location of the said customers, as appropriate. 3. Aspen will then allocate the value of the Transitory Rebate as follows: <ol style="list-style-type: none"> a. Public hospital sales: Aspen will pay the Transitory Rebate to the autonomous regions (and, if applicable, the two autonomous cities). In particular: <ol style="list-style-type: none"> i. Aspen will allocate the Transitory Rebate to each public hospital based on Aspen's internal and Aspen's Agents' sales data. ii. Aspen will calculate the amount payable to each region (and city, if applicable) by aggregating the parts of the Transitory Rebate attributable to individual hospitals by region based on the location of the customer/hospital. iii. Aspen will pay the aggregated amounts, calculated as per above, to the relevant autonomous region (and if applicable

24. SPAIN	
	<p>autonomous city). In this regard, Aspen will inform each autonomous region (and, if applicable, autonomous city) about the amount of the Transitory Rebate attributable to their respective region/city and make the payment based on payment instructions to be provided by the latter.</p> <p>b. Private sales: Aspen will allocate the Transitory Rebate to each private customer, including private hospitals and clinics, based on Aspen's internal and Aspen's Agents' sales data. Aspen will pay the Transitory Rebate to its private customers via credit notes.</p>
Fall-back Recipient	<p>If it is not possible to pay some or all of the Transitory Rebate to the Appropriate Beneficiary, and if the Regulatory Authority does not nominate an alternative recipient (as laid down in paragraph 9) of the Commitments), Aspen will, pursuant to paragraph 9) of the Commitments, pay any remainder amount to the following Fall-back Recipient: the Ministry of Health (Ministerio de Sanidad).</p>

25. SWEDEN	
Appropriate Beneficiary	Aspen will pay the Transitory Rebate for hospital (in-patient) sales to the 21 regional governments (regionala regeringar) and for out-patients sales to the national government (nationell regering). See Table A below.
Methodology	<p>As there are several entities in Sweden ultimately paying or reimbursing the Products' purchase price, Aspen will pay the Transitory Rebate to the relevant entities based on the allocation set out below.</p> <ol style="list-style-type: none"> 1. After the Entry Into Force of the Commitments, Aspen will calculate the amount of the Transitory Rebate based on based on paragraph 9) of the Commitments; 2. Aspen will inform the Ministry of Social Affairs of the amount of the Transitory Rebate and request the relevant bank account details for the payment; 3. Aspen will make the payment of the Transitory Rebate to the Ministry of Social Affairs, both for hospital (in-patient) and out-patient sales, to "<i>Kammarkollegiets BG 5052-5781</i>" with reference to "<i>Anslag 1:5 Bidrag för läkemedelsförmånerna</i>" (Contributing for Pharmaceutical Benefits); 4. The Ministry of Social Affairs will allocate the Transitory Rebate for in-patient sales to the 21 regional governments (regionala regeringar) and for out-patients sales to the national government (nationell regering), as appropriate, based on data on in-patient and out-patient sales from the Dental and Pharmaceutical Benefits Agency (Tandvårds- och läkemedelsförmånsverket - TLV).
Fall-back Recipient	If it is not possible to pay some or all of the Transitory Rebate to the Appropriate Beneficiary, and if the Regulatory Authority does not nominate an alternative recipient (as laid down in paragraph 9) of the Commitments), Aspen will, pursuant to paragraph 9) of the Commitments, pay any remainder amount to the following Fall-back Recipient: Regionala Cancercentrum I Samverkan.

26. UNITED KINGDOM	
Appropriate Beneficiary	Aspen will pay the Transitory Rebate to the National Health Service (NHS).
Fall-back Recipient	If it is not possible to pay some or all of the Transitory Rebate to the Appropriate Beneficiary, and if the Regulatory Authority does not nominate an alternative recipient (as laid down in paragraph 9) of the Commitments), Aspen will, pursuant to paragraph 9) of the Commitments, pay any remainder amount to the following Fall-back Recipient: UCH Macmillan Cancer Centre.

Section 2: Residual Fall-back Recipient

- 12) Under no circumstances will Aspen retain any revenues attributable to or resulting from the application of a price level that exceeds the Reduced Net Prices as from the Effective Date until the Implementation Date.
- 13) Any amount of the Transitory Rebate that has not been allocated to the Appropriate Beneficiaries pursuant to paragraph 9) i) to v) of the Commitments, will be paid to the following Residual Fall-back Recipient: European Cancer Patient Coalition.

Table A – Appropriate Beneficiaries

Relevant Country	Appropriate Beneficiaries	
Austria	<p>For the Social Health Insurance Funds (SHIFs), the Umbrella Organisation of Social Security Institution (UO-SSI) (Dachverband der Sozialversicherungsträger) (SV)</p> <ol style="list-style-type: none"> 1. Österreichische Gesundheitskasse – ÖGK 2. Sozialversicherungsanstalt der Selbständigen – SVS 3. Versicherungsanstalt öffentlich Bediensteter, Eisenbahnen und Bergbau – BVAEB 	<p>Länder:</p> <ol style="list-style-type: none"> 1. Vienna (Wien) 2. Lower Austria (Niederösterreich) 3. Upper Austria (Oberösterreich) 4. Styria (Steiermark) 5. Tyrol (Tirol) 6. Carinthia (Kärnten) 7. Salzburg 8. Vorarlberg 9. Burgenland
Belgium	Federal Government (Belgische federale regering/ Gouvernement fédéral belge) via the National Institute for Health and Disability Insurance (Rijksinstituut voor ziekte- en invaliditeitsverzekering (RIZIV) / Institut national d'assurance maladie-invalidité (INAMI))	
Bulgaria	National Health Insurance Fund (NHIF) (Национална здравноосигурителна каса) (H3OK)	
Czech Republic	<p>Seven Public Health Insurance Funds (Fondy veřejného zdravotního pojištění) (PHIFs)</p> <ol style="list-style-type: none"> 1. Všeobecná zdravotní pojišťovna 2. Oborová zdravotní pojišťovna 3. Vojenská zdravotní pojišťovna 4. Česká průmyslová zdravotní pojišťovna 5. Zaměstnanecká pojišťovna Škoda 6. Zdravotní pojišťovna Ministertsva vnitra 7. RBP zdravotní pojišťovna 	Individuals on the basis of co-payment

Relevant Country	Appropriate Beneficiaries	
Denmark	Five Regions (Regioner) 1. Hovedstaden 2. Midtjylland 3. Nordjylland 4. Sjælland 5. Syddanmark	
Estonia	Estonian Health Insurance Fund (EHIF) (Eesti Haigekassa)	
Finland	In-patient use: 21 Hospital districts (21 Sairaanhoidopiiri) 1. Etelä-Karjalan sairaanhoidopiiri 2. Etelä-Pohjanmaan sairaanhoidopiiri 3. Etelä-Savon sairaanhoidopiiri 4. Helsingin ja Uudenmaan sairaanhoidopiiri 5. Itä-Savon sairaanhoidopiiri 6. Kainuun sairaanhoidopiiri 7. Kanta-Hämeen sairaanhoidopiiri 8. Keski-Pohjanmaan sairaanhoidopiiri 9. Keski-Suomen sairaanhoidopiiri 10. Kymenlaakson sairaanhoidopiiris 11. Lapin sairaanhoidopiiri 12. Länsi-Pohjan sairaanhoidopiiri 13. Pirkanmaan sairaanhoidopiiri 14. Pohjois-Karjalan sairaanhoidopiiri 15. Pohjois-Pohjanmaan sairaanhoidopiiri 16. Pohjois-Savon sairaanhoidopiiri 17. Päijät-Hämeen sairaanhoidopiiri 18. Satakunnan sairaanhoidopiiri 19. Vaasan sairaanhoidopiiri 20. Varsinais-Suomen sairaanhoidopiiri 21. Ålands hälso- och sjukvård	Out-patient use: Social Insurance Institution of Finland (Kela)

Relevant Country	Appropriate Beneficiaries				
France	Health insurance system (Agence Centrale des Organismes de Securite Sociale) (ACOSS)				
Germany	<p>GKVs (Gesetzliche Krankenversicherungen)</p> <p>AOK Krankenkassen</p> <ol style="list-style-type: none"> 1. AOK Baden-Württemberg 2. AOK Bayern 3. AOK Bremen / Bremerhaven 4. AOK Hessen 5. AOK Niedersachsen 6. AOK Nordost 7. AOK NordWest 8. AOK PLUS – Sachsen / Thüringen 9. AOK Rheinland/Hamburg 10. AOK Rheinland-Pfalz/Saarland 11. AOK Sachsen-Anhalt Ersatzkassen & Knappschaft 12. Barmer GEK 13. DAK-Gesundheit 14. HEK – Hanseatische Krankenkasse 15. hkk Erste Gesundheit 16. KKH Kaufmännische Krankenkasse 17. Techniker Krankenkasse 18. Knappschaft <p>Innungskrankenkassen</p> <ol style="list-style-type: none"> 19. BIG direkt gesund 20. IKK Brandenburg und Berlin 21. IKK classic 22. IKK gesund plus 23. IKK Nord 24. IKK Südwest 	<p>PKVs (Private Krankenversicherungen)</p> <ol style="list-style-type: none"> 1. Allianz Private Krankenversicherungs- AG 2. ALTE OLDENBURGER Krankenversicherung AG 3. ALTE OLDENBURGER Krankenversicherung von 1927 V.V.a.G 4. ARAG Krankenversicherungs- AG 5. AXA Krankenversicherung AG 6. Barmenia Krankenversicherung AG 7. Barmenia Versicherungen a.G. 8. Bayerische Beamtenkrankenkasse Aktiengesellschaft 9. Concordia Krankenversicherungs -AG 10. Continentale Krankenversicherung a.G. 11. Debeka Krankenversicherungsverein a.G. 12. DEVK Krankenversicherungs- Aktiengesellschaft 	Beihilfe	Two Closed Funds affiliated to the PKV-Verband; Krankenversicherung der Bundesbahnbeamten (KVB) and Postbeamtenkrankenkasse (PBEAKK)	Individuals on the basis of co-payment

Relevant Country	Appropriate Beneficiaries				
	Betriebskrankenkassen 25. actimonda 26. atlas BKK ahlmann 27. Audi BKK 28. Bahn BKK 29. Die BERGISCHE 30. Bertelsmann BKK 31. BKK 24 32. BKK Achenbach Buschhütten 33. BKK Akzo Nobel 34. BKK Diakonie 35. BKK Dürkopp Adler 36. BKK EUREGIO 37. BKK exklusiv 38. BKK Faber-Castell & Partner 39. BKK firmus 40. BKK Freudenberg 41. BKK GILDEMEISTER SEIDENSTICKER 42. BKK Herford Minden Ravensberg 43. BKK HERKULES 44. BKK Linde 45. BKK Melitta Plus 46. BKK MOBIL OIL 47. BKK PFAFF 48. BKK Pfalz 49. BKK ProVita 50. BKK Public 51. BKK Schwarzwald-Baar-Heuberg 52. BKK Scheufelen 53. BKK Technoform 54. BKK Textilgruppe Hof 55. BKK Verkehrsbau Union (VBU)	13. DKV Deutsche Krankenversicherung AG 14. Envivas Krankenversicherung AG 15. ERGO Krankenversicherung AG 16. FREIE ARZT-UND MEDIZINKASSE der Angehörigen der Berufsfeuerwehr und der Polizei VVaG 17. Generali Deutschland Krankenversicherung AG 18. Gothaer Krankenversicherung AG 19. HALLESCHE Krankenversicherung auf Gegenseitigkeit 20. HanseMercur Krankenversicherung AG 21. HanseMercur Speziale Krankenversicherung AG 22. HUK-COBURG- Krankenversicherung AG 23. INTER Krankenversicherung AG 24. Krankenunterstützungskasse der Berufsfeuerwehr Hannover (KUK) 25. Landeskrankenhilfe V.V.a.G. 26. LIGA Krankenversicherung katholischer Priester VVaG			

Relevant Country	Appropriate Beneficiaries				
	56. BKK VDN 57. BKK VerbundPlus 58. BKK Werra-Meissner 59. BKK Wirtschaft & Finanzen 60. BKK ZF & Partner 61. Bosch BKK 62. Debeka BKK 63. Die Continentale BKK 64. Energie-BKK 65. Heimat Krankenkasse 66. mhplus Krankenkasse 67. Novitas BKK 68. pronova BKK 69. R + V BKK 70. Salus BKK 71. SBK – Siemens BKK 72. Schwenninger Krankenkasse 73. SECURVITA 74. SIEMAG BKK 75. SKD BKK 76. TUI BKK 77. VIACTIV Krankenkasse 78. WMF BKK Geschlossene Betriebskrankenkassen 79. BKK BPW Bergische Achsen KG 80. BKK B. Braun Aesculap 81. BKK der MTU Friedrichshafen 82. BKK Deutsche Bank AG 83. BKK EVM 84. BKK EWE 85. BKK GRILLO-WERKE AG 86. BKK Groz-Beckert	27. LVM Krankenversicherung - AG 28. Mecklenburgische Krankenversicherungs-AG 29. Münchener Verein Krankenversicherung a.G. 30. NÜRNBERGER Krankenversicherung AG 31. ottonova Krankenversicherung AG 32. Provinzial Krankenversicherung Hannover AG 33. R + V Krankenversicherung AG 34. SIGNAL IDUNA Krankenversicherung a.G. 35. SONO Krankenversicherung a.G. 36. ST. MARTINUS Priesterverein der Diözese Rottenburg-Stuttgart – Kranken- und Sterbekasse (KSK) – V.V.a.G. 37. Süddeutsche Krankenversicherung a.G. 38. Union Krankenversicherung AG 39. uniVersa Krankenversicherung a.G. 40. Versicherer im Raum der Kirchen Krankenversicherung AG			

Relevant Country	Appropriate Beneficiaries				
	87. BKK KARL MAYER 88. Koenig & Bauer BKK 89. Kronen BKK 90. BKK MAHLE 91. BKK Miele 92. BKK Rieker.Ricosta.Weisser 93. BKK Pricewaterhouse-Coopers 94. BKK RWE 95. BKK Salzgitter 96. BKK STADT AUGSBURG 97. BKK Voralb 98. BKK Würth 99. BMW BKK 100. Daimler BKK 101. Ernst & Young BKK 102. Merck BKK 103. Südzucker BKK 104. Wieland BKK	41. vigo Krankenversicherung VVaG 42. Württembergische Krankenversicherung AG			
Greece	Pharmaceutical Research and Technology company (IFET) (Ινστιτούτο Φαρμακευτικής Έρευνας & Τεχνολογίας ΑΕ (ΙΦΕΤ))				
Iceland	Icelandic Health Insurance (NHS) (Sjúkratryggingar Íslands)				
Ireland	Health Service Executive (HSE) (Feidhmeannacht na Seirbhíse Sláinte)				
Latvia	National Health Service (Nacionālais veselības dienests) (NVD)				
Lithuania	Compulsory Health Insurance Fund (Valstybinė Ligonijų Kasa) (VLK)				
Malta	Ministry for Health (Ministeru għas-Saħħa)				
Netherlands	24 Health Insurance Companies (Zorgverzekeraars) divided into 11 groups: 1. ASR Nederland N.V. 2. Coöperatie Menzis U.A., including:				

Relevant Country	Appropriate Beneficiaries
	<ul style="list-style-type: none"> a. Anderzorg NV 3. Zilveren Kruis Zorgverzekeringen N.V., including: <ul style="list-style-type: none"> a. Interpolis Zorgverzekeringen N.V. b. De Friesland Zorgverzekeraar N.V. c. FBTO Zorgverzekeringen N.V. d. Avéro Achmea Zorgverzekeringen NV 4. CZ groep Zorgverzekeraar U.A., including: <ul style="list-style-type: none"> a. OHRA Zlektkosten b. OHRA Zorgverzekeringen c. Nationale-Nederlanden 5. OWM DSW Zorgverzekeraar U.A., including: <ul style="list-style-type: none"> a. Stad Holland Zorgverzekeraar OWM U.A. 6. Eno Zorgverzekeraar NV 7. EUCARE Insurance PCC Ltd 8. iptiQ Life S.A. 9. ONVZ Holding B.V. 10. Coöperatie VGZ UA, including: <ul style="list-style-type: none"> a. IZA Zorgverzekering b. IZZ Zorgverzekering c. UMC Zorgverzekering d. Unive Zorgverzekering 11. OWM Zorgverzekeraar Zorg en Zekerheid u.a.
Norway	Regional Health Authorities (Regionalt helseforetak) (RHF) <ul style="list-style-type: none"> 1. Helse Vest 2. Helse Midt-Norge 3. Helse Nord 4. Helse Sor-Ost
Poland	National Health Fund (Narodowy Fundusz Zdrowia) (NFZ)
Portugal	Hospitals

Relevant Country	Appropriate Beneficiaries	
Romania	The Romanian National Health Insurance House (NHIH) (Casa Națională de Asigurări de Sănătate) (CNAS)	
Slovakia	<p>Three Public Health Insurance Funds (PHIFs) (Verejné zdravotné poisťovne):</p> <ol style="list-style-type: none"> 1. Všeobecná zdravotná poisťovňa, a.s, 2. Dôvera zdravotná poisťovňa, a.s. 3. Union zdravotná poisťovňa, a. s. 	
Slovenia	Health Insurance Institute of Slovenia (Zavod za zdravstveno zavarovanje Slovenije)	
Spain	<p>Public hospital care: seventeen autonomous regions (Comunidades Autónomas) and (if applicable) two autonomous cities managed by the National Health Management Institute (Instituto Nacional de Gestión Sanitaria-INGESA)</p> <ol style="list-style-type: none"> 1. Andalusia (Andalucía) 2. Valencia 3. Catalonia (Cataluña) 4. Balearic Islands (Islas Baleares) 5. Canary Islands (Islas Canarias) 6. Galicia 7. Basque Country (Euskadi) 8. Madrid City and Province (Madrid ciudad v provincial) 9. Asturias 10. Cantabria 11. Murcia 12. Navarre 13. La Rioja 14. Aragon (Aragón) 15. Castille and Leon (Castilla y León) 16. Castilla La Mancha 17. Extremadura (Extremadura) 	<p>Aspen's private (non-public) customers, including private hospitals and clinics, and, if applicable, mutual benefit societies for national civil servants, i.e., MUFACE (General Administration), MUGEJU (Justice Administration) and ISFAS (Defense Administration) to the extent not covered in the payment of the Transitory Rebate to the private customers.</p>

Relevant Country	Appropriate Beneficiaries	
Sweden	<p>In-patient use: 21 regional governments (County Council, County, Region) (Inpatient användning: 21 regionala regeringar (landsting, län, region))</p> <ol style="list-style-type: none"> 1. Blekinge County Council, Blekinge, Region Blekinge 2. Dalarna County Council, Dalarna, Region Dalarna 3. Gävleborg County Council, Gävleborg, Region Gävleborg 4. Gotland Municipality, Gotland, Region Gotland 5. Halland County Council, Halland, Region Halland 6. Jämtland County Council, Jämtland, Region Jämtland Härjedalen 7. Jönköping County Council, Jönköping, Region Jönköpings län 8. Kalmar County Council, Kalmar, Region Kalmar län 9. Kronoberg County Council, Kronoberg, Region Kronoberg 10. Norrbotten County Council, Norrbotten, Region Norrbotten 11. Skåne Regional Council, Skåne, Region Skåne 12. Stockholm County Council, Stockholm, Region Stockholm 13. Södermanland County Council, Södermanland, Region Sörmland 14. Uppsala County Council, Uppsala, Region Uppsala 15. Värmland County Council, Värmland, Region Värmland 16. Västerbotten County Council, Västerbotten, Region Västerbotten 17. Västernorrland County Council, Västernorrland, Region Västernorrland 18. Västmanland County Council, Västmanland, Region Västmanland 19. Västra Götaland Regional Council, Västra Götaland, Västra Götalandsregionen 20. Örebro County Council, Örebro, Region Örebro län 21. Östergötland County Council, Östergötland, Region Östergötland 	<p>Out-patient use: national government (Öppenvård: nationell regering)</p>
United Kingdom	National Health Service (NHS)	

Case AT.40394 – Aspen

Appendix 2

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Appendix 2 – Identification and allocation of indirect costs

This Appendix describes the application of the method in allocating Aspen’s Indirect Costs to the Relevant Products in Aspen’s FY2019 for the purposes of application of the Commitments. In particular, this Appendix describes the process through which the two main types of Indirect Costs are identified and allocated to the Relevant Products and Relevant Countries, namely:

- I. Marketing authorisation costs (“**Marketing Authorisation Costs**”); and
- II. Indirect costs excluding Marketing Authorisation Costs (“**Other Indirect Costs**”), which also include overheads costs

I. Marketing Authorisation Costs

- 1) Marketing Authorisations are required for the commercialisation of each country-medicine-format. Once the product’s dossier (Marketing Authorisation documents) has been created, it needs to be constantly updated and adapted to national requirements, which change regularly. This is necessary to ensure accurate life cycle management, as well as compliance and transparency of regulatory actions. Activities related to the maintenance of products’ dossiers are listed in the European Medical Agency’s post authorization guidance for Marketing Authorisation holders and European Commission’s ‘Variations Guidelines’ 2013/C 223/01.
- 2) To identify and allocate Marketing Authorisation Costs, the general method set out below should be followed:
 - i) First, identify the entities that perform regulatory activities for the Relevant Products in the Relevant Countries.
 - ii) Second, identify any costs incurred by these entities that are related, either in whole or in part, to regulatory activities for the Relevant Products in the Relevant Countries.
 - iii) Third, for each type of cost remaining after the second step, identify the products and geographies that these costs relate to (across which the costs need to be “spread”). This will be used to determine the denominator of the allocation calculation.
 - iv) Fourth, split the costs between ‘variable’ and ‘fixed’ costs, where ‘variable’ costs are those which are considered dependent on product sales and ‘fixed’ costs are those which are considered independent of product sales.
 - v) Fifth, allocate the ‘variable’ costs to the Relevant Products in the Relevant Countries based on an allocation based on Cost of Goods (“**Cost of Goods Allocation**”). Where Cost of Goods data is not available,¹ use an allocation based on Volumes (“**Volume Allocation**”).²
 - vi) Finally, allocate the ‘fixed’ Marketing Authorisation costs to the Relevant Products in the Relevant Countries based on the number of Marketing Authorisations associated with the Relevant Products in each of the Relevant Countries. Spread this across the Relevant Products and Relevant Countries based on a Volume Allocation.

¹ Cost of Goods data may not be available at a sufficiently granular level to allow the allocation of costs by Cost of Goods. For example, in FY2019 we relied on Volumes for allocating AHC administrative costs across Europe CIS and MENA and to allocate the Other Indirect Costs incurred by Aspen Europe entities in the Relevant Countries to the Relevant Products.

² An Indirect Cost incurred by an Aspen Group entity that operates within a given product and geographic scope is allocated by volume to the Relevant Products in the Relevant Countries by (i) first dividing the Indirect Cost by the total *volumes* generated by the products within the product scope in the geographic areas within the geographic scope, and then by (ii) multiplying this ratio by the *volumes* of the Relevant Products in the Relevant Countries. To allocate this cost to the Relevant Products by Cost of Goods sold, instead, we need to (i) divide the Indirect Cost by the total *Cost of Goods Sold* of the products within the product scope in the geographic areas within the geographic scope, and then (ii) multiply this ratio by the *Cost of Goods Sold* of the Relevant Products in the Relevant Countries.

- 3) In FY2019, within the Aspen Group, these regulatory activities in the EEA were performed by APTL and AGI. The methodology for allocating these costs for each of these entities in FY2019 is described below.

APTL

- 4) In FY2019, staff costs related to obtaining and maintaining Marketing Authorisations for Global Brand Products³ were recorded in APTL.
- 5) The Marketing Authorisation Costs for the Relevant Products in the Relevant Countries in APTL were identified and allocated as follows:
- i) First, all of the operating expenses in APTL related to regulatory activities. Hence, no operating expenses from APTL were excluded.
 - ii) Second, the regulatory expenses were split into the following functions/departments:
 - (1) Pharmacovigilance;
 - (2) Quality Assurance;
 - (3) Medical Information;
 - (4) Medical Affairs;
 - (5) Regulatory Affairs;
 - (6) Artwork; and
 - (7) Learning Academy.

Aspen's systems did not report costs at the granular function level. The total costs were therefore split based on budgeted costs. Any support costs (for example, IT) were split across the different functions in the same proportions.
 - iii) Third, regulatory expenses incurred in relation to EU regulations were estimated as [...] of total regulatory expenses;⁴
 - iv) Finally, these costs were split between 'variable' and 'fixed' costs, where:
 - (1) the costs of Pharmacovigilance and Quality Assurance were identified as 'variable' costs; and
 - (2) The balance, being the costs of Medical Information, Medical Affairs, Regulatory Affairs, Artwork and Learning Academy were considered 'fixed' costs.
- 6) The 'variable' and 'fixed' costs related to all Global Brand Products in the EEA, so they needed to be "spread" across all Global Brand products in the EEA. In particular, these costs were allocated to the Relevant Products in the Relevant Countries as follows:
- i) The 'variable' costs were allocated to the Relevant Products in the Relevant Countries based on a Cost of Goods Allocation;
 - ii) The 'fixed' costs were allocated in two steps:
 - (1) First, the total amount of Marketing Authorisation Costs for all the Relevant Products in the Relevant Countries in combination was calculated based on the number of Marketing Authorisations; and
 - (2) This total amount was then spread across the Relevant Products and the Relevant Countries based on a Volume Allocation.

³ The Global Brand Products are a group of Aspen products that are commercialised across a broad range of territories.

⁴ Aspen has assessed that [...] of its technical salary costs relate to the EU and that it is reasonable to apply this percentage to both its support salaries and other operating expenses that are linked to the services it provides.

AGI

- 7) In FY2019, AGI was responsible for the supply and quality management of the Relevant Products globally, which included performing certain regulatory activities, such as stability testing.
- 8) The costs recorded in AGI included costs for technical projects, stability testing, quality assurance and regulatory affairs related to the Relevant Products. They were collected based on invoices maintained by the AGI strategic projects team.
- 9) These costs related to the Relevant Products globally, so they needed to be “spread” across all Relevant Products globally. In particular, as these were all ‘fixed’ costs, which were not dependent on product sales, they were allocated to the Relevant Products in the Relevant Countries in two steps:
 - i) First, the total pool of Marketing Authorisation Costs to allocate across all the Relevant Products in the Relevant Countries was calculated based on the number of Marketing Authorisations held for the Relevant Products in the Relevant Countries; and
 - ii) This total pool was then allocated to the Relevant Products in the Relevant Countries based on a Volume Allocation.

II. Other Indirect Costs

- 10) Having allocated Marketing Authorisation costs, the Other Indirect Costs consist of the operating expenditures of entities within the Aspen Group that provide services or undertake the management of, or are associated with, the sale of the Relevant Products in the Relevant Countries (excluding maintaining marketing authorizations). These costs exclude depreciation, amortization or impairment charges relating to tangible fixed assets or intangible assets.
- 11) To identify and allocate these costs, the general method set out below should be followed:
 - i) First, identify the entities that provide services or undertake the management of, or are associated with, the sale of the Relevant Products in the Relevant Countries.
 - ii) Second, exclude any costs incurred by these entities that are not related to providing services for or managing, or are not associated with, the sale of the Relevant Products in the Relevant Countries.
 - iii) Third, for each type of cost remaining after the second step, identify the products and geographies that these costs relate to (across which the costs need to be “spread”). This will be used to determine the denominator of the allocation calculation.
 - iv) Finally, allocate these costs to the Relevant Products in the Relevant Countries based on a Cost of Goods Allocation. If Cost of Goods data is not available,⁵ use a Volume Allocation.
- 12) In FY2019, there were four main categories of Other Indirect Costs:
 - i) **Overheads:** Operating expenses incurred by entities in the Aspen Group, excluding Aspen Europe;
 - ii) **General Office Aspen Europe:** Operating expenses incurred by Aspen Europe entities and recorded against the portfolio “General Office”;
 - iii) **Cosmos Aspen Europe:** Operating expenses incurred by Aspen Europe entities and recorded against the portfolio “COSMOS”;⁶ and

⁵ See footnote 1.

⁶ The Cosmos portfolio comprises the Relevant Products as well as Seprin, Trandate and Kemadrin.

- iv) **Nightingale Aspen Europe:** Operating expenses incurred by Aspen Europe entities and recorded against the portfolio “Nightingale”.
- 13) The costs in each of these categories were allocated to the Relevant Products in the Relevant Countries as follows.

Overheads

The Aspen Group entities that incurred overhead costs in FY2019 and the product and geographic scope over which the costs needed to be “spread” are set out in Table 1.

Table 1: Indirect costs to allocate to the Products, by Aspen Group entity and product and geographic scope of their operations in FY2019

Entity	Product and geographic scope
APHL	
Administrative activities	All products, globally
AGI	
Costs associated with the Cosmos portfolio	Cosmos portfolio, globally
Administrative costs	Global Brand products, globally
AHC	
Commercial activities	Global Brand products, Europe CIS
Administrative activities	Global Brand products, Europe, Commonwealth of Independent States, Middle East and North Africa
APIL	
Administrative activities	Global Brand products, Europe CIS

Note: Cost of Goods Sold data is not available in aggregate at Europe CIS level but is available at EEA level. In order to allocate indirect costs as much as possible by Cost of Goods Sold, Aspen relied on Cost of Goods data at EEA level as a proxy.

- 14) Overheads costs were allocated to the Relevant Products in the Relevant Countries based on a Cost of Goods Allocation or, where Cost of Goods data was not available,⁷ based on a Volume Allocation.

General Office Aspen Europe

- 15) In FY2019, General Office costs in the Aspen Europe entities were classified as “General Office” in Aspen’s accounting records. These costs were only incurred in relation to the Global Brand Products, so they needed to be “spread” across all Global Brand products. The geographic area over which these costs needed to be “spread” depended on the geographic scope of the activities of the Aspen Group entity that incurred these costs, as set out in Table 2.

Table 2: Aspen Europe Entities and the corresponding geographic scope in FY2019

Aspen Europe Entity	Geographic scope
AFR	France
AGR	Germany
ANET	Netherlands
APOL	Poland
BAUT	Austria
BBEL	Belgium
BBGR	Bulgaria
BCZE	Czech Republic
BDNK	Denmark
AESP	Spain and Portugal

⁷ Cost of Goods Sold data was not available for allocating AHC’s administrative costs in Europe CIS and MENA; these costs were therefore allocated based on a Volume Allocation.

Aspen Europe Entity	Geographic scope
BGBR	United Kingdom
BGRC	Greece and Cyprus
BHUN	Hungary
BROU	Romania
BSVK	Slovakia
BSVN	Slovenia
BFIN	Finland
BNOR	Norway
BSWE	Sweden
BEHQ	EEA

- 16) These costs were allocated to the Relevant Products in the Relevant Countries based on a Volume Allocation as Costs of Goods data was not available.

Cosmos Aspen Europe

- 17) In FY2019, Operating expenses specific to the Cosmos portfolio were classified as “Cosmos” in Aspen Europe entities’ accounting records. As these costs are specific to the Cosmos portfolio, they needed to be “spread” across the Cosmos Products. The geographic area over which these costs needed to be “spread” depended on the geographic scope of the activities of the Aspen Group entity that incurred these costs, as set out in Table 2.
- 18) These costs were allocated to the Relevant Products in the Relevant Countries based on a Volume Allocation as Costs of Goods data was not available.

Nightingale Aspen Europe

- 19) In FY2019, some of the General Office Operating expenses entries were recorded as “Nightingale” costs rather than “General Office” costs. This is because Nightingale was the largest portfolio of products in Europe and the “Nightingale” cost code was therefore used as the default cost code. This cost category therefore included costs that related generally to the Aspen Group’s European activities, as well as costs specifically related to project Nightingale.
- 20) These costs were identified and allocated to the Relevant Products in the Relevant Countries as follows:
- i) First, the amount of Nightingale costs that related to the Cosmos portfolio was estimated by:
 - (1) multiplying the total Nightingale costs by the percentage of the Aspen Group Global Brand Products’ net revenues in the EEA that were generated by the Nightingale products to identify the costs related to Nightingale products. This amount was then deducted from the total Nightingale costs; and
 - (2) having excluded the costs related directly to Nightingale products, the remaining costs are multiplied by the percentage of the Aspen Group Global Brand Products (excluding Nightingale)’s Volumes in the EEA that are generated by the Cosmos products.
 - ii) Second, having estimated the costs relating to the Cosmos Portfolio, these costs were “spread” across the Cosmos portfolio and over the geographic area corresponding to the geographic scope of the activities of the Aspen Europe entity that incurred these costs, as set out in Table 2. In particular, these costs were allocated to the Relevant Products in the Relevant Countries based on a Volume Allocation.

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Appendix 3

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Appendix 3 – Gross and List Prices for Relevant Products with List Prices Commercialised in FY2019¹

Relevant Country ²	Reduced Prices ³	Alkeran IV	Alkeran tab 25	Alkeran tab 50	Lanvis 25	Leukeran 25	Leukeran 50	Myleran 25	Myleran 100	Purinethol 25
Austria	Gross Price	-	€ 27.06	-	€ 106.00	€ 17.45	-	-	€ 91.75	€ 9.76
	Listed MSP	-	€ 27.06	-	€ 106.00	€ 17.45	-	-	€ 91.75	€ 9.76
	Listed WSP	-	€ 29.90	-	€ 115.01	€ 19.28	-	-	€ 99.55	€ 10.98
	Listed PSP	-	€ 43.41	-	€ 149.28	€ 28.64	-	-	€ 134.69	€ 16.30
Belgium	Gross Price	[€ 32.33 – 35.92]	[€ 23.48 – 26.08]	-	[€ 76.30 – 84.78]	-	[€ 19.31 – 21.46]	-	[€ 52.16 – 57.96]	[€ 11.41 – 12.68]
	Listed MSP	€ 35.92	€ 26.08	-	€ 84.78	-	€ 21.46	-	€ 57.96	€ 12.68
	Listed WSP	-	-	-	-	-	-	-	-	-
	Listed PSP	€ 47.43	€ 36.23	-	€ 101.93	-	€ 30.96	-	€ 72.53	€ 20.96
Bulgaria	Gross Price	-	-	-	-	[€ 8.48 – 9.98]	-	-	-	[€ 13.03 – 15.33]
	Listed MSP	-	-	-	-	€ 9.98	-	-	-	€ 15.33
	Listed WSP	-	-	-	-	€ 10.58	-	-	-	€ 16.25
	Listed PSP	-	-	-	-	€ 14.85	-	-	-	€ 22.45
Czech Republic	Gross Price	€ 27.73	€ 46.80	-	€ 106.00	€ 16.25	-	-	€ 86.51	€ 22.60
	Listed MSP	€ 27.73	€ 46.80	-	€ 106.00	€ 16.25	-	-	€ 86.51	€ 22.60
	Listed WSP	-	-	-	-	-	-	-	-	-
	Listed PSP	€ 38.88	€ 64.06	-	€ 139.74	€ 23.59	-	-	€ 114.91	€ 32.12
Denmark	Gross Price	-	[€ 38.53 – 40.99]	-	-	[€ 34.55 – 36.75]	-	-	-	-
	Listed MSP	-	-	-	-	-	-	-	-	-

¹ The local currency Gross and List Prices will be determined on the Entry Into Force based on the average exchange rate set by the European Central Bank (ECB), as published in the ECB's website, in force during the last completed calendar month preceding the Entry Into Force. For the avoidance of doubt, changes in the exchange rate after the Entry Into Force are not taken into account.

² For confidentiality reasons, Gross Price levels have as appropriate been replaced by ranges.

³ "MSP" stands for Manufacturer Selling Price, "WSP" stands for Wholesaler Selling Price and "PSP" stands for Pharmacy Selling Price. The prices highlighted in green will be included in Aspen's pricing applications.

Relevant Country ²	Reduced Prices ³	Alkeran IV	Alkeran tab 25	Alkeran tab 50	Lanvis 25	Leukeran 25	Leukeran 50	Myleran 25	Myleran 100	Purinethol 25
	Listed WSP	-	€ 40.99	-	-	€ 36.75	-	-	-	-
	Listed PSP	-	€ 57.54	-	-	€ 51.83	-	-	-	-
Estonia ⁴	Gross Price	-	[€ 51.76 – 56]	-	-	[€ 38.70 – 42]	-	-	[€ 76.95 – 84]	[€ 36.00 – 39]
	Listed MSP	-	-	-	-	-	-	-	-	-
	Listed WSP	-	-	-	-	-	-	-	-	-
	Listed PSP	-	€ 63.68	-	-	€ 49.97	-	-	€ 91.97	€ 46.48
Finland	Gross Price	-	[€ 26.30 – 27.27]	-	-	[€ 13.26 – 13.75]	-	-	-	-
	Listed MSP ⁵	-	-	-	-	-	-	-	-	-
	Listed WSP	-	€ 27.27	-	-	€ 13.75	-	-	-	-
	Listed PSP	-	€ 41.51	-	-	€ 21.43	-	-	-	-
France	Gross Price	-	-	[€ 25.38 – 33.01]	[€ 69.26 – 90.07]	-	-	[€ 38.85 – 50.53]	-	[€ 8.32 – 10.82]
	Listed MSP	-	-	€ 33.01	€ 90.07	-	-	€ 50.53	-	€ 10.82
	Listed WSP	-	-	-	-	-	-	-	-	-
	Listed PSP	-	-	€ 38.21	-	-	-	€ 58.29	-	€ 12.63
Germany	Gross Price	[€ 30.27 – 30.98]	[€ 23.39 – 24.18]	[€ 31.97 – 33.93]	[€ 75.85 – 79.43]	[€ 13.08 – 13.49]	[€ 18.93 – 19.98]	[€ 23.90 – 33.50]	[€ 48.95 – 50.72]	[€ 11.46 – 12.33]
	Listed MSP	€ 30.98	€ 24.18	€ 33.93	€ 79.43	€ 13.49	€ 19.98	€ 33.50	€ 50.72	€ 12.33
	Listed WSP	€ 32.66	€ 25.64	€ 35.70	€ 82.63	€ 14.61	€ 21.31	€ 35.26	€ 53.02	€ 13.42
	Listed PSP	€ 50.22	€ 41.62	€ 53.94	€ 111.47	€ 28.10	€ 36.31	€ 53.40	€ 75.17	€ 26.63
Iceland	Gross Price	-	[€ 18.55 – 20]	-	-	-	-	-	[€ 91.96 – 101]	[€ 36.00 – 40]
	Listed MSP	-	-	-	-	-	-	-	-	-
	Listed WSP	-	€ 20.96	-	-	-	-	-	€ 103.91	€ 40.68
	Listed PSP	-	€ 40.15	-	-	-	-	-	€ 155.71	€ 67.62
Ireland	Gross Price	[€ 36.00 – 39]	[€ 47.17 – 52]	-	-	[€ 26.40 – 28.52]	-	-	-	[€ 13.41 – 14.48]

⁴ The “MSP” is effectively Aspen’s Gross Price; it is not a listed price in this Member State.

⁵ The “MSP” is effectively Aspen’s Gross Price; it is not a listed price in this Member State.

Relevant Country ²	Reduced Prices ³	Alkeran IV	Alkeran tab 25	Alkeran tab 50	Lanvis 25	Leukeran 25	Leukeran 50	Myleran 25	Myleran 100	Purinethol 25
	Listed MSP ⁶	-	-	-	-	-	-	-	-	-
	Listed WSP	€ 42.35	€ 52.84	-	-	€ 28.52	-	-	-	€ 14.48
	Listed PSP	-	-	-	-	-	-	-	-	-
Latvia ⁷	Gross Price	-	[€ 50.99 – 53.03]	-	-	[€ 14.23 – 15.88]	-	-	-	-
	Listed MSP	-	-	-	-	-	-	-	-	-
	Listed WSP	-	€ 53.03	-	-	€ 15.88	-	-	-	-
	Listed PSP	-	€ 65.15	-	-	€ 20.99	-	-	-	-
Lithuania	Gross Price	-	-	-	-	[€ 38.70 – 39.80]	-	-	[€ 80.12 – 81.37]	[€ 23.72 – 24.72]
	Listed MSP	-	-	-	-	€ 39.80	-	-	€ 81.37	€ 24.72
	Listed WSP	-	-	-	-	€ 40.31	-	-	€ 83.82	€ 25.23
	Listed PSP	-	-	-	-	€ 43.38	-	-	€ 93.37	€ 27.54
Netherlands	Gross Price	[€ 26.22 – 28.04]	[€ 16.38 – 17.52]	-	[€ 55.21 – 59.05]	[€ 10.28 – 10.99]	-	-	[€ 61.97 – 66.28]	[€ 7.79 – 8.33]
	Listed MSP ⁸	-	-	-	-	-	-	-	-	-
	Listed WSP	€ 28.04	€ 17.52	-	€ 59.05	€ 10.99	-	-	€ 66.28	€ 8.33
	Listed PSP	-	-	-	-	-	-	-	-	-
Norway	Gross Price	-	[€ 21.26 – 22.62]	-	-	[€ 22.88 – 24.34]	-	-	-	[€ 13.44 – 14.30]
	Listed MSP	-	-	-	-	-	-	-	-	-
	Listed WSP	-	€ 22.62	-	-	€ 24.34	-	-	-	€ 14.30
	Listed PSP	-	€ 35.15	-	-	€ 37.20	-	-	-	€ 24.40
Poland	Gross Price	-	€ 23.05	-	€ 85.50	€ 16.34	-	€ 38.07	€ 75.77	-
	Listed MSP	-	€ 23.05	-	€ 85.50	€ 16.34	-	€ 38.07	€ 75.77	-
	Listed WSP	-	€ 24.20	-	€ 89.78	€ 17.16	-	€ 39.97	€ 79.56	-
	Listed PSP	-	€ 29.46	-	€ 102.35	€ 21.45	-	€ 47.22	-	-

⁶ The “MSP” is effectively Aspen’s Gross Price; it is not a listed price in this Member State.

⁷ The “MSP” is effectively Aspen’s Gross Price; it is not a listed price in this Member State.

⁸ The “MSP” is effectively Aspen’s Gross Price; it is not a listed price in this Member State.

Relevant Country ²	Reduced Prices ³	Alkeran IV	Alkeran tab 25	Alkeran tab 50	Lanvis 25	Leukeran 25	Leukeran 50	Myleran 25	Myleran 100	Purinethol 25
Romania	Gross Price	-	[€ 20.66 – 31.78]	-	[€ 87.35 – 124.88]	[€ 16.58 – 25.91]	-	-	-	[€ 8.66 – 13.53]
	Listed MSP	-	€ 31.78	-	€ 124.88	€ 25.91	-	-	-	€ 13.53
	Listed WSP	-	€ 34.96	-	€ 131.32	€ 28.50	-	-	-	€ 15.16
	Listed PSP	-	€ 42.68	-	€ 151.32	€ 34.79	-	-	-	€ 19.16
Slovenia	Gross Price	-	[€ 32.53 – 35.08]	-	[€ 102.04 – 108.98]	[€ 19.85 – 21.60]	-	[€ 32.23 – 34.76]	[€ 49.93 – 53.58]	[€ 36.00 – 38.77]
	Listed MSP ⁹	-	-	-	-	-	-	-	-	-
	Listed WSP	-	€ 35.08	-	€ 108.98	€ 21.60	-	€ 34.76	€ 53.58	€ 38.77
	Listed PSP	-	-	-	-	-	-	-	-	-
Sweden	Gross Price	-	[€ 20.02 – 20.58]	[€ 27.27 – 28.03]	[€ 67.83 – 69.71]	[€ 17.63 – 18.12]	[€ 26.45 – 27.18]	-	[€ 79.75 – 81.96]	[€ 11.39 – 11.70]
	Listed MSP	-	-	-	-	-	-	-	-	-
	Listed WSP	-	€ 20.58	€ 28.03	€ 69.71	€ 18.12	€ 27.18	-	€ 81.96	€ 11.70
	Listed PSP	-	€ 25.58	€ 33.25	€ 75.79	€ 23.04	€ 32.38	-	€ 88.29	€ 17.60
United Kingdom	Gross Price	[€ 26.71 – 30]	[€ 16.52 – 18]	-	[€ 76.55 – 84]	[€ 11.18 – 12]	-	[€ 14.46 – 15]	-	[€ 9.44 – 10]
	Listed MSP	-	-	-	-	-	-	-	-	-
	Listed WSP	€ 30.53	€ 18.88	-	€ 87.49	€ 12.78	-	€ 16.53	-	€ 10.79
	Listed PSP	-	-	-	-	-	-	-	-	-

⁹ The “MSP” reflects also the distributor margin; the “MSP” is not a listed price in this Member State.

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Appendix 4

AT.40394 – Aspen**Appendix 4 – Regulatory Authorities**

Regulatory Authorities to receive Aspen's pricing applications	
Relevant Country	Regulatory Authority
Austria	Pricing Commission of the Federal Ministry of Social Affairs, Health, Care and Consumer Protection (Bundesministerium für Soziales, Gesundheit, Pflege und Konsumentenschutz)
Belgium	Pricing agency of the Economy Ministry (Service Public Fédéral Economie, P.M.E., Classes moyennes et Energie / Federale Overheidsdienst Economie, K.M.O., Middenstand en Energie) Reimbursement agency of the National Institute for Health and Disability Insurance (Institut National d'Assurance Maladie Invalidité / Rijksinstituut voor ziekte- en invaliditeitsverzekering - INAMI/RIZIV)
Bulgaria	National Council for Prices and Reimbursement of medicinal products (NCPR) (национален съвет по цени и реимбурсиране на лекарствените продукти – НСЦРПН)
Czech Republic	State Institute for Drug Control (Státní ústav pro kontrolu léčiv – SÚKL)
Denmark	Danish Medicines Agency (Laegemiddelstyrelsen) (via DKMANet platform)
Estonia	State Agency of Medicines (Ravimiamet)
Finland	Pharmaceuticals Pricing Board (Hila)
France	Comité économique des produits de santé (CEPS)
Germany	Federal Ministry of Health (Bundesministerium für Gesundheit – BMG) ¹
Iceland	Icelandic Medicine Pricing and Reimbursement Committee (Lyfjagreiðslunefnd)
Ireland	Health Service Executive (HSE) (Feidhmeannacht na Seirbhíse Sláinte)
Latvia	National Health Service (Nacionālā veselības dienesta – NVD)
Lithuania	State Health Insurance Fund (Valstybinė Ligonijų Kasa – VLK)
Netherlands	Z-Index: in representation of The Dutch Healthcare Authority (Nederlandse Zorgautoriteit – NZa)
Norway	Norwegian Medicines Agency (Legemiddelverket) Norwegian Drug Procurement Corporation (Sykehusinnkjøp) for hospital products
Poland	Ministry of Health (Ministerstwo Zdrowia – MZ)
Romania	The National Health Insurance House of Romania (Casa Națională de Asigurări de Sănătate – CNAS) for reimbursement Ministry of Health (Ministerul Sanatatii) for pricing
Slovenia	Public Agency of the Republic of Slovenia for Medicines and Medical Devices (Javna agencija Republike Slovenije za zdravila in medicinske pripomočke – JAZMP)
Sweden	Swedish Dental and Pharmaceutical Benefits Agency (Tandvårds-och läkemedelsförmånsverket – TLV)

¹ Aspen will update the prices with Informationsstelle für Arzneispezialitäten GmbH (IFA).

Regulatory Authorities to receive Aspen's pricing applications	
Relevant Country	Regulatory Authority
United Kingdom	Department of Health and Social Care (DHSC)

Pricing and reimbursement Regulatory Authorities (if different)	
Relevant Country	Regulatory Authority
Austria	Umbrella Organisation of the Social Security Institution (UO-SSI) (Dachverband der Sozialversicherungsträger) for outpatients

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Appendix 5

AT. 40394 – Aspen**Appendix 5 – Gross Prices for Relevant Products without List Prices Commercialised in FY2019¹**

Relevant Country ²	Alkeran IV	Alkeran tab 25	Alkeran tab 50	Lanvis 25	Leukeran 25	Leukeran 50	Myleran 25	Myleran 100	Purinethol 25
Austria	€ 28.65	-	-	-	-	-	-	-	-
Bulgaria	-	-	-	€ 70.51	-	-	-	-	-
Denmark	-	-	-	€ 93.43	-	-	-	€ 91.96	€ 21.28
Finland	€ 33.11	-	-	€ 72.51	-	-	-	€ 64.44	-
France	[€ 24.15 – 32]	-	-	-	-	-	-	-	-
Greece	-	€ 18.83	-	-	€ 14.83	-	-	-	-
Iceland	€ 27.53	-	-	-	-	-	-	-	-
Malta	-	-	-	-	-	-	-	-	€ 6.51
Norway	-	-	-	€ 85.78	-	-	-	€ 63.99	-
Poland	€ 23.71	-	-	-	-	-	-	-	-
Portugal³	-	[€ 18.24 – 22]	-	-	[€ 8.32 – 10]	-	-	-	-
Slovakia	€ 27.66	€ 51.76	-	€ 106.00	€ 38.70	-	-	-	€ 36.00
Spain	-	-	€ 31.91	-	-	€ 22.85	-	€ 60.72	€ 12.07
Sweden	€ 23.82	-	-	-	-	-	-	-	-

¹ The local currency Gross Prices will be determined on the Entry Into Force based on the average exchange rate set by the European Central Bank (ECB), as published in the ECB's website, in force during the last completed calendar month preceding the Entry Into Force. For the avoidance of doubt, changes in the exchange rate after the Entry Into Force are not taken into account.

² For confidentiality reasons, Gross Price levels have as appropriate been replaced by ranges.

³ The listed Products in Spain and Portugal, including Products for which Aspen holds marketing authorisations, are sold using foreign packs at Gross Prices.

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Appendix 6

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Appendix 6 – Prices for Relevant Products Commercialised or re-Commercialised since 1 July 2019 (section B.3 of the Commitments)¹

1. Relevant Products with List Prices

Relevant Country ²	Reduced Prices ³	Alkeran IV	Alkeran tab 25	Alkeran tab 50	Lanvis 25	Leukeran 25	Leukeran 50	Myleran 25	Myleran 100	Purinethol 25
Iceland	Gross Price	-	-	-	-	[€ 34.55 – 38]	-	-	-	-
	Listed MSP	-	-	-	-	-	-	-	-	-
	Listed WSP	-	-	-	-	€ 39.04	-	-	-	-
	Listed PSP	-	-	-	-	€ 65.33	-	-	-	-
Lithuania	Gross Price	-	[€ 27.06 – 28.26]	-	[€ 85.78 – 87.08]	-	-	-	-	-
	Listed MSP	-	€ 28.26	-	€ 87.08	-	-	-	-	-
	Listed WSP	-	€ 28.77	-	€ 89.53	-	-	-	-	-
	Listed PSP	-	€ 35.56	-	€ 99.36	-	-	-	-	-
Romania	Gross Price	-	-	-	-	-	-	-	[€ 76.95 – 120.23]	-
	Listed MSP	-	-	-	-	-	-	-	€ 120.23	-
	Listed WSP	-	-	-	-	-	-	-	€ 126.67	-
	Listed PSP	-	-	-	-	-	-	-	€ 146.25	-
Spain	Gross Price	[€ 23.71 – 32.44]	-	-	-	-	-	-	-	-
	Listed MSP	€ 32.44	-	-	-	-	-	-	-	-
	Listed WSP	-	-	-	-	-	-	-	-	-
	Listed PSP	€ 50.63	-	-	-	-	-	-	-	-

¹ The local currency Gross and List Prices will be determined on the Entry Into Force based on the average exchange rate set by the European Central Bank (ECB), as published in the ECB's website, in force during the last completed calendar month preceding the Entry Into Force. For the avoidance of doubt, changes in the exchange rate after the Entry Into Force are not taken into account.

² For confidentiality reasons, Gross Price levels have as appropriate been replaced by ranges.

³ "MSP" stands for Manufacturer Selling Price, "WSP" stands for Wholesaler Selling Price and "PSP" stands for Pharmacy Selling Price. The prices highlighted in green will be included in Aspen's pricing applications.

2. Relevant Products without List Prices

Relevant Country	Reduced Prices	Alkeran IV	Alkeran tab 25	Alkeran tab 50	Lanvis 25	Leukeran 25	Leukeran 50	Myleran 25	Myleran 100	Purinethol 25
Estonia	Gross Price	€ 23.71	-	-	-	-	-	-	-	-
Hungary	Gross Price	€ 36.00	-	-	-	[€13.26 – 18]	-	-	-	-
Slovakia	Gross Price	-	-	-	-	-	-	-	€ 91.75	-
Spain	Gross Price	-	€ 23.05	-	€ 69.26	-	-	-	-	-