Case AT.40394 – Aspen

PROPOSAL FOR 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 the Merger Regulation and in light of the Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings.

API: Active Pharmaceutical Ingredient.

Appropriate Beneficiary: that Person(s) identified in the enclosed Annex 1 which will receive the Transitory Rebates pursuant to paragraph 9) below.

Aspen: Aspen Pharmacare Holdings Ltd[1], together with all Affiliated Undertakings, including but not limited to Aspen Global Incorporated[2], Aspen Pharma Trading Limited[3], Aspen Pharma Ireland Limited[4], Aspen Europe GmbH[5] (including its branches in various Member States), Aspen Bad Oldesloe GmbH[6] and Aspen Healthcare FZ LLC[7].

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.

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 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 45) increased costs will only be taken

1 A company incorporated in the Republic of South Africa.

2 A company incorporated in Mauritius.

3 A company incorporated in Ireland.

4 A company incorporated in Ireland.

5 A company incorporated in Germany.

6 A company incorporated in Germany.

7 A company incorporated in the United Arab Emirates.

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 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 Annex 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.

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

Gross Price: the EUR price invoiced by Aspen to its customers for the Relevant Products in the Relevant Country net of sales 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.

Gross Sales: the aggregate of the gross EUR amount reflected on 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 authorizations) excluding depreciation, amortization or impairment charges relating to tangible fixed assets or intangible assets.

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 institutions or healthcare 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 competition 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.

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 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.

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 the Effective Date, or at any time during the Commitment Period.

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 each case 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. For purposes of the definition of the Cost of Goods, where a Relevant Product is manufactured by Aspen, the lower of either the Standard Cost or the Benchmark Year Costs will be taken into account, subject to costs increases described in the definition of Costs of Goods above.

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

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

Transitory Rebate or Transitory Rebates: shall mean transitory rebate(s) as defined in paragraph 9 below of the 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 1 below for each Relevant Product in each Relevant Country for the relevant dosage form and pack size identified. Aspen shall not, directly or indirectly, refer to these Commitments in its communication with Member State 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 10 years from the Entry Into Force of the Commitments.

Table 1: Reduced Net Prices for the Relevant Products[8] (EUR)[9]

Relevant Country	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	-	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	-	-	-	-
Iceland	27.53	18.55	-	-	-	-	-	91.96	36.00
Ireland	36.00	47.17	-	-	26.40	-	-	-	13.41
Latvia	-	50.99	-	-	14.23	-	-	-	-
Lithuania	-	-	-	-	38.70	-	-	80.12	23.72
Malta	-	-	-	-	-	-	-	-	6.51
Netherlands	26.22	16.38	-	55.21	10.28	-	-	61.97	7.79
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	-	-	-	8.66
Slovakia	27.66	51.76	-	106.00	38.70	-	-	-	36.00
Slovenia	-	32.53	-	102.04	19.85	-	32.23	49.93	36.00
Spain	-	-	31.91	-	-	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) within one week of the Entry Into Force, or as soon as possible thereafter as permitted 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 Annex 3 in order to achieve the Reduced Net Prices where List Prices exist. Aspen will submit applications to the Regulatory Authorities identified in Annex 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 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

[8] Please refer to paragraphs 11, 12 and 14 for Relevant Products and/or pack sizes (re-)commercialised during the Commitment Period.

[9] Please refer to the definition of Reduced Net Price above. The Reduced Net Price does not include fees and mark-ups attributable to distributors, pharmacies or other intermediaries.

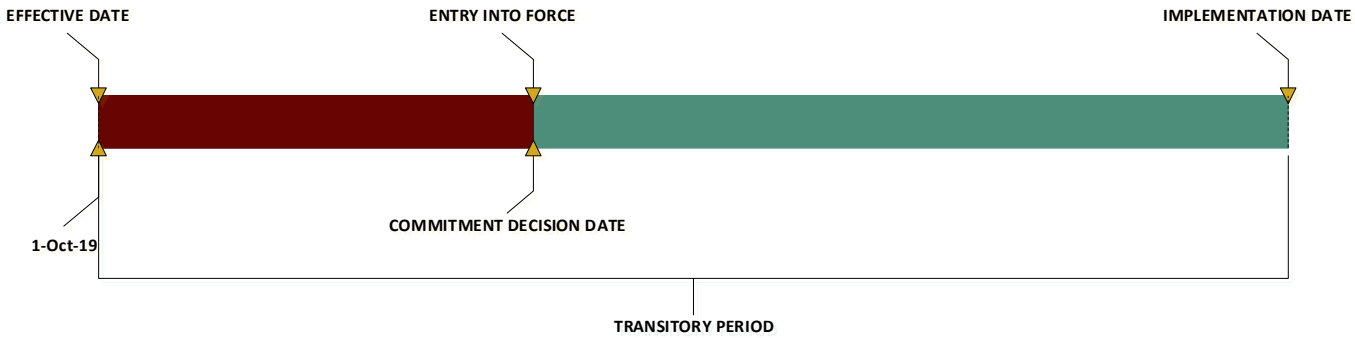
to ensure the expedient reduction of the List Price. Where feasible pursuant to local laws and procedures, Aspen will pursue an expedited process pursuant to the relevant laws and procedures. Aspen will immediately inform its Agents and customers of the approval of the new List Prices; or

ii) where a List Price does not exist (i.e. the Relevant Countries listed in Annex 5) Aspen will reduce Gross Prices of the Relevant Products as soon as possible after the Entry Into Force to the level identified in Annex 5 in order to achieve the Reduced Net Price, subject to any pre-existing contractual/tender obligations. During the period from the Entry into Force 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 ultimately no higher Net Prices than the Reduced Net Prices, Aspen undertakes, for all Relevant Countries, to make a payment to each Appropriate Beneficiary (as listed in Annex 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 and paid for the 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 to the payment of a Transitory Rebate include the payment of such interest.



i) Notification obligations:

(1) Immediately after Entry into Force, Aspen will write to each Appropriate Beneficiary: (a) informing it that a Transitory Rebate is owed to it; (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 the Appropriate Beneficiary informing of the amount of the Transitory Rebate and that the payment shall include interest calculated pursuant to paragraph 9) and requesting confirmation of the modalities for payment.

ii) Time limits for payment: the Transitory Rebate shall be paid within 90 days after informing the Appropriate Beneficiary about the amount of the Transitory Rebate. This time limit can be extended by 60 additional days subject to an extension request submitted by the Appropriate Beneficiary within the original 90 days 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 30 days and a last written reminder 10 days before the end of the given period.

iii) Fall-back: in the event that an Appropriate Beneficiary has not provided instructions for some or all of the payment of a Transitory Rebate pursuant to paragraph 9)i), or if it is for other reasons impossible to pay all or part of a Transitory Rebate to the Appropriate Beneficiary, Aspen will notify the Regulatory Authority in the Relevant Country. If Aspen after 30 days still has not received any instructions for payment to the Appropriate Beneficiary and if the Regulatory Authority has not nominated a fall-back recipient, Aspen will transfer any non-paid parts of the Transitory Rebate to the recipient identified in Annex 1 as fall-back recipient ("Fall-back Recipient") instead of to the Appropriate Beneficiary. If the Regulatory Authority has nominated an alternative fall-back recipient pursuant to this paragraph 9)iii), Aspen will pay the Transitory Rebate instead to this alternative fall-back recipient.

iv) Instalment in case of major delay: if Aspen has not yet transferred the Transitory Rebate within one 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 the few Relevant Countries where patient co-payments exists, Aspen shall, within two months of the Entry into Force, according to the modalities set out in Annex 1 for each country concerned, take appropriate steps to effectively inform the patients who made a co-payment during the Transitory Period. This information will explain the precise period for which the patients can claim

payment of a Transitory Rebate, indicate the approximate amount of the Transitory Rebate per pack to be paid, and invite the patients concerned to make a claim for a payment of the Transitory Rebate by Aspen. Aspen will take appropriate steps to effectively communicate regular reminders to the patients who made co-payments. If Aspen has not received a claim 18 months after having first taken steps to inform the patients, Aspen will transfer the balance of the Transitory Rebate to the specific Fall-back Recipient identified in Annex 1.

vi) 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 to the Appropriate Beneficiaries and 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 Annex 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 as otherwise allowed by applicable laws, at Gross Prices set at the level identified in Annex 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 FY2019 and between the end of FY2019 and the Effective Date, but Commercialised by Aspen in that Relevant Country before FY2019, if Aspen were to decide to Commercialise these Relevant Products in that Relevant Country after the Effective Date, 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 1 for the same Relevant Product and the same pack size in the 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 forecasted volume included in Aspen's final Product Launch Request Form that formed the basis for its decision to launch the Launch Product.

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 1 during the Commitment Period, the Reduced Net Price of the new pack size shall be calculated by applying the Reduced Net Price of the same pack size in the 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 Price in relation to the new pack size should be calculated proportionally per unit by reference to the next largest pack size. In this context, any adjustment of the Reduced Net Price as calculated above derived from a significant increase of Aspen's Direct Costs will be assessed under paragraph 45) and subject to the conditions set out therein.

15) Aspen shall not circumvent or attempt to circumvent the Commitments either directly or indirectly by any act or omission. In particular, Aspen will as of the Effective Date, refrain from practices which have the equivalent object or effect of increasing the price of any of the Relevant Products in any Relevant Country above the levels identified in the Commitments.

Supply commitments

16) 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, for the duration of the effects of such events in the Supply Commitment Period, Aspen commits to:

i) maintain the registration of the marketing authorizations 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 authorization and/or through foreign pack supply. Aspen will ensure appropriate and continued supplies so that the needs in the Relevant Countries are covered.

17) 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, 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 16)ii), and unless Aspen decides 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 one year before this discontinuation is to take effect; and

ii) offers for sale its marketing authorization at least one year before discontinuing to Commercialise a Relevant Product in a Relevant Country. Regarding the sale, Aspen commits to ensure that the marketing authorization 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 authorizations of the Relevant Products does not occur within a period of six months of Aspen offering the relevant marketing authorization for sale, Aspen will offer to sell the marketing authorization(s) concerned at no minimum price. As long as Aspen has not sold and effectively transferred its marketing authorization, Aspen commits to maintain, during the Commitment Period, the registration of its marketing authorization for as long as possible under applicable laws.

18) Aspen will not to withdraw the marketing authorization for any Relevant Product in any Relevant Country prior to the Entry into Force.

19) Aspen shall not circumvent or attempt to circumvent the Commitments either directly or indirectly by any act or omission. In particular, Aspen will as of the Effective Date, refrain from practices which have the equivalent object or effect of reducing the number of tablets or vials of the Relevant Products Commercialised in any Relevant Country.

Section C. Trustee

I. Appointment procedure

20) Aspen shall appoint a Trustee to carry out the functions specified in these Commitments.

21) 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.

22) 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

23) No later than 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 21) 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

24) 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

25) 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 21) and 24).

Trustee nominated by the Commission

26) 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 of the Trustee

27) The Trustee shall act on behalf of the Commission to ensure Aspen's compliance with the Commitments and assume the duties specified in 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 conditions and obligations attached to the Commitment Decision. Aspen may not give instructions to the Trustee.

Duties and obligations of the Trustee

28) The Trustee shall:

i) propose in its first report to the Commission a detailed work plan describing how it intends to monitor compliance with the obligations and conditions attached to the Commitment Decision;

ii) 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 with the timeframe set by the Trustee;

iii) act as a contact point for any requests by third parties in relation to the Commitments;

iv) within 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 then issues or problems which may have risen in the execution of the Trustee's obligations, in particular any issues of non-compliance by Aspen with the Commitments and a proposal for a detailed work plan described in point i) above for the remainder of the then Financial Year;

v) provide to the Commission (sending Aspen a non-confidential copy at the same time) a bi-monthly status report regarding the payment of the Transitory Rebate pursuant to paragraph 9) until the total amount of the Transitory Rebate for each Relevant Country has been paid;

vi) without undue delay, inform the Commission about the last reminder to an Appropriate Beneficiary sent 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);

vii) 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 Product in any Relevant Country;

viii) 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 pursuant to paragraphs 9)i - vi) has not been fully made, 10 working days prior to Aspen's payment of the remaining amount of the Transitory Rebate to the residual fall-back recipient;

ix) within 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, in particular any issues of non-compliance by Aspen with the Commitments;

(2) review and assessment of the progress of the implementation of the Reduced Net Prices;

(3) the Gross Sales, the Net Sales and the volume of sales of the Relevant Products in the Relevant Countries;

(4) the sale of a marketing authorization of a Relevant Product in a Relevant Country; and

(5) a proposal for a detailed work plan described at point i) above for the then current Financial Year.

29) 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

30) 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 so 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;

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 Annex 2 of the Commitments.

31) All confidential information is provided by Aspen to the Trustee subject to due respect by the Trustee of the confidentiality of such information.

32) 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.

33) Aspen will inform the Trustee of the full set of necessary steps to inform patients of co-payment amounts owed and consult thereon with the Trustee before transferring any remaining balance of the Transitory Rebate, as may exist, to the specific Fall-back Recipient identified in Annex 1. Aspen will immediately send copies of all its communications under paragraph 9) to the Trustee.

34) 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.

35) 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.

36) 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*.

37) 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.

38) 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

39) 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.

40) If the Trustee is discharged according to paragraph 39), 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 20) - 26) (inclusive).

41) Unless removed in accordance with paragraph 39), 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

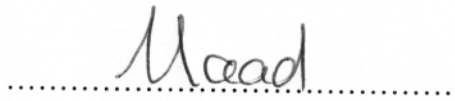
42) The Commission may extend the time periods foreseen for the implementation of the Commitments in response to a reasoned request from Aspen or, in appropriate cases, on its own initiative. Where Aspen requests an extension of a time period, it shall submit a reasoned request to the Commission no later than 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.

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) 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.

45) Without prejudice to paragraphs 43) and 44) above, 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. 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 Annex 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).

46) Reasoned requests 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.



duly authorised for and on behalf of Aspen Pharmacare Holdings Limited

Stephen Saad

Group Chief Executive

List of Annexes

Annex	Title	Description
Annex 1	Payment of Transitory Rebate and Appropriate Beneficiaries	Information on the payment of the Transitory Rebate to Appropriate Beneficiaries and/or Fall-back Recipients per Relevant Country
Annex 2	Methodology note on the 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
Annex 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
Annex 4	Regulatory Authorities	A list of Regulatory Authorities per Relevant Country before which Aspen should submit its pricing applications
Annex 5	Gross Prices for Relevant Products without List Prices Commercialised in FY2019	Relevant Products without List Prices Commercialised in FY2019, and reduced Gross Prices to achieve the Reduced Net Prices

Case AT. 40394 – Aspen

Annex 1

Case AT.40394 – Aspen

Annex 1 – Payment of the Transitory Rebate and Appropriate Beneficiaries

1) This Annex forms an integral part of Aspen's Proposed Commitments to the European Commission and governs the implementation of the Transitory Rebate payments pursuant to paragraph 9 of the Proposed Commitments.

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 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 Relevant Product in the Relevant Country concerned.

3) This Annex 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 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 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 Commitment Decision, Aspen will write to each Appropriate Beneficiary informing it that a Transitory Rebate is owed to it and informing it of the estimated amount of the Transitory Rebate and how it will be determined. Immediately after the Implementation Date, Aspen will then write to the Appropriate Beneficiary informing of the amount of the Transitory Rebate. Aspen will pay the Transitory Rebate within 90 days after it has informed the Appropriate Beneficiary about the amount of the Transitory Rebate. The above deadline can be extended by 60 additional days subject to an extension request submitted by the Appropriate Beneficiary within the original 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 30 days and a last written reminder 10 days before the end of the given period.

7) For the payment of the Transitory Rebate amount attributable to co-payments, 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 18 months after having first taken steps to inform the patients.

Fall-back Recipients

8) In the event that an Appropriate Beneficiary has not provided instructions for some or all of the payment of a Transitory Rebate or if it was for other reasons impossible to pay all or part of the Transitory Rebate to the Appropriate Beneficiary, Aspen will notify the Regulatory Authority in the Relevant Country. If after 30 days following that notification Aspen still has not received any instructions for payment to the Appropriate Beneficiary and if the Regulatory Authority does not nominate any Fall-back Recipient, Aspen will transfer any non-paid parts of the Transitory Rebate to the Fall-back Recipient identified in this Annex instead of to the Appropriate Beneficiary. If the Regulatory Authority has nominated an alternative fall-back recipient ("Alternative Fall-back Recipient"), Aspen will pay the Transitory Rebate instead to this Alternative Fall-back Recipient.

Residual fall-back recipient

9) If the above mechanisms fail, the Proposed 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 Fall-back Recipients pursuant to paragraph 9 i) to v) of the Proposed Commitment; this residual fall-back recipient is included in section 2 of this Annex.

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 1 below.
Methodology	As there are several entities in Austria, listed in Table 1 of this Annex, 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. This allocation is based on the following assumptions: 1. Each of the Länder and SHIFs provide coverage for oncology treatment; 2. Each of the Länder and SHIFs have the same per capita incidence of relevant types of cancer; 3. The per capita split of out-patient and in-patient funding is materially the same between the Länder; and 4. The hospital and retail channels have equal pricing. Aspen will use the following methodology to allocate the Transitory Rebate: 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. If this is not possible, Aspen will ask UO-SSI for instructions to pay the respective amounts to the SHIFs directly. 2. Aspen will pay the remaining 40% of the Transitory Rebate to the Länder. Aspen will contact the Land holding the chair in the Bundesrat (Vorsitzführendes Bundesland) during the relevant part of the Transitory Period. Aspen will invite the respective Land to internally consult with the other Länder to provide Aspen with instructions on how to distribute and pay the Transitory Rebate to the different Länder. Aspen will first contact the Land Salzburg that is holding the chair in the Bundesrat in the 2nd half of 2020. If necessary, Aspen will also contact the Land which will hold the chair in the Bundesrat in the 1st half of 2021, i.e. the Land Steiermark.
Fall-back Recipient	If it is not possible to pay some or all of the Transitory Rebate to any of the Appropriate Beneficiaries, and if the Regulatory Authority does not nominate a Fall-back Recipient (as laid down in paragraph 9 of the Proposed Commitments), Aspen will, pursuant to paragraph 9 of the Proposed 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 a Fall-back Recipient (as laid down in paragraph 9 of the Proposed Commitments), Aspen will, pursuant to paragraph 9 of the Proposed 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 the 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 a Fall-back Recipient (as laid down in paragraph 9 of the Proposed Commitments), Aspen will, pursuant to paragraph 9 of the Proposed 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 1 below.
Methodology	As there are several entities in the Czech Republic ultimately paying or reimbursing the Products' purchase price, as well as individual patients that 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. 1. Firstly, Aspen will calculate the Transitory Rebate applicable to individual patients who made a co-payment: i. Aspen will cooperate with the PHIFs in order to determine the amount of the co-payments. The co-payment amount per pack under the current 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 Transitory Rebate applicable to co-payment claims. ii. Aspen will further cooperate with the PHIFs to notify the patients who made co-payments for any of the Products between 1 October 2019 and the Implementation Date (Implementation Date will be the date of the reduction of the List Prices). iii. Within two months from the Entry into Force of the Proposed Commitments, in order to notify patients that may have made co-payments Aspen will: a) publish a notice in doctors' offices, including oncologists/haematologists' practices, and in pharmacies. 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 Transitory Rebate as calculated in 1.i. above; b) ask the doctors, in particular oncologists/hematologists and pharmacists, to inform the patients that made co-payments during the mentioned period that they would be entitled to a rebate from the Transitory Rebate as calculated in 1.i. above; c) make available flyers with the information set out in 1.iv. to the doctors, pharmacists, oncologists/hematologists so as to hand out to the

4. CZECH REPUBLIC	
	patients to whom they are prescribing and dispensing the Relevant Products. iv. The notice referred to in 1.ii. and 1.iii. will contain: a) clear information on the reasons why the patients can claim part of the Transitory Rebate; b) the period for which they are entitled to the Transitory Rebate; c) the amount of the Transitory Rebate per pack for those who made a co-payment; d) information on how the patients can claim the Transitory Rebate; and e) the date by which they can claim the Transitory Rebate. v. The patients should substantiate the claim with a proof of purchasing; however Aspen will accept the proof of co-payment provided by the PHIFs for the patients who claim the Transitory Rebate and will not request any additional receipt. vi. The individual patients who made a co-payment will have a period of 18 months to claim the Transitory Rebate. This period will start running from the date Aspen has first taken steps to inform the patients. 2. Secondly, Aspen will calculate and allocate the Transitory Rebate to be paid to the PHIFs: i. Aspen will calculate the value of the total Transitory Rebate based on Aspen's internal and LSP 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 Transitory Rebate applicable to patients who made co-payments calculated in accordance with 1. i. above. The remaining balance of the Transitory Rebate will be paid to the PHIFs; for this purpose, Aspen will contact PHIFs or the "National registry of reimbursed services" to obtain reimbursement data to allocate the appropriate amounts; iii. 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, applying the following macro assumptions: a) Each PHIF provides coverage for oncology treatment; and

4. CZECH REPUBLIC	
	b) Each PHIF has the same per capita incidence of relevant types of cancer.
Fall-back recipient	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 a Fall-back Recipient (as laid down in paragraph 9 of the Proposed Commitments), Aspen will, pursuant to paragraph 9 of the Proposed Commitments, pay any remainder amount to the following Fall-back Recipient: PHIF – "redistribution account" ("redistribuční účet"). For individual patients who incurred a co-payment cost: after the expiry of 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.

5. DENMARK	
Appropriate Beneficiary	Aspen will pay the Transitory Rebate to the six Regions (Regioner) via Amgros. See Table 1 below.
Methodology	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. Aspen will pay the Transitory Rebate centrally to Amgros who will channel the money to the ultimate payer in the Regions. In order to determine the share of the money between the different Regions, Aspen will provide the following information to Amgros: 1. Total amount of the Transitory Rebate; 2. The Relevant Products (Alkeran tablets; Leukeran, Lanvis, Myleran and Purinethol); and 3. The Transitory Period. If Amgros does not have the data to determine the share of money between different Regions, Aspen will allocate the Transitory Rebate between the six Regions based on the value of hospital sales: 1. Aspen will calculate the total sales for the Relevant Products by Region; 2. Aspen will calculate the Transitory Rebate per Product per Region for Alkeran tablets and Leukeran; 3. Aspen will, using the combined sales per Region for Alkeran tablets and Leukeran, proportionately allocate the Transitory Rebates for Lanvis and Myleran to the Regions. The above allocation methodology makes the following macro assumptions: 1. Each Region provides coverage for oncology treatment; 2. Each Region has the same per capita incidence of relevant types of cancer; and 3. Lanvis, Myleran and Purinethol have the same regional and channel split as the weighted average of Alkeran tablets and Leukeran.
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 a Fall-back Recipient (as laid down in paragraph 9 of the Proposed Commitments), Aspen will, pursuant to paragraph 9 of the Proposed 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 a Fall-back Recipient (as laid down in paragraph 9 of the Proposed Commitments), Aspen will, pursuant to paragraph 9 of the Proposed 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 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 1 below.
Methodology	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. 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 LSP and wholesaler data. 2. Aspen will use the combined sales per channel/Region to proportionately allocate the Transitory Rebates for any special license 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 a Fall-back Recipient (as laid down in paragraph 9 of the Proposed Commitments), Aspen will, pursuant to paragraph 9 of the Proposed 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 (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 a Fall-back Recipient (as laid down in paragraph 9 of the Proposed Commitments), Aspen will, pursuant to paragraph 9 of the Proposed Commitments, pay any remainder amount to the following Fall-back Recipient: French National Cancer Institute (Institut National Du Cancer).

9. GERMANY	
Appropriate Beneficiary	Aspen will pay the Transitory Rebate to the following Appropriate Beneficiaries: 1. For the GKVs (Gesetzliche Krankenversicherungen), the GKV-Spitzenverband; 2. For the PKVs (Private Krankenversicherungen), the Verband der Privaten Krankenversicherung (PKV-Verband); 3. Two 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. See Table 1 below.
Methodology	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. 1. Firstly, Aspen will calculate the Transitory Rebate applicable to individual patients who made a co-payment: i. Aspen will make all efforts to cooperate with the GKVs and the PKVs in order to determine the amount of the co-payment. The co-payment amount per pack under the existing prices will then 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 Transitory Rebate applicable to co-payment claims. ii. Aspen will make all efforts to cooperate with the GKVs and PKVs to 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). iii. Within two months from the Entry into Force of the Proposed Commitments, in order to notify patients that may have made co-payments Aspen will: a) publish a notice in doctors' offices, including oncologists/haematologists' practices, and in pharmacies. In accordance with the notice, any patients

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	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 Transitory rebate as calculated in 1.i. above; b) ask the doctors, in particular oncologists/hematologists and pharmacists, to inform the patients that made co-payments during the mentioned period that they would be entitled to a rebate from the Transitory Rebate as calculated in 1.i. above; c) make available flyers with the information set out in 1.iv. to the doctors, pharmacists, oncologists/hematologists so as to hand out to the patients to whom they are prescribing and dispensing the Relevant Products. iv. The notice referred to in 1.iii. will contain: a) clear information on the reasons why the patients can claim part of the Transitory Rebate; b) the period for which they are entitled to part of the Transitory Rebate; c) the amount of the Transitory Rebate per pack for those who made a co-payment; d) information on how the patients can claim the Transitory Rebate, and e) the date by which they can claim the Transitory Rebate. v. The patients should substantiate the claim with a proof of purchasing; however, Aspen will accept the proof of co-payment provided by the GKVs and the PKVs for the patients who claim the Transitory Rebate and will not request any additional receipt. vi. The individual patients who made a co-payment will have a period of 18 months to claim the Transitory Rebate. This period will start running from the date Aspen has first taken steps to inform the patients. 2. Secondly Aspen will calculate and allocate the Transitory Rebate to be paid to the GKVs, PKVs, the Closed Funds and Beihilfe: i. Aspen will calculate the value of the total Transitory Rebate based on Aspen's internal and LSP 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;

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	ii. From this value Aspen will deduct the value of the Transitory 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 GKVs, PKVs, the Closed Funds and Beihilfe. Aspen will pay the Transitory Rebate on a per capita basis as follows : i. Aspen will identify the number of patients covered by GKVs, PKVs, Closed Funds (and each fund within those categories, if appropriate); ii. On the assumption that each fund within the GKVs, PKVs 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 membership data; iii. 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 pay the Transitory Rebates at an aggregate level to the following entities: 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 v. Aspen will approach the above-mentioned entities in order to arrange for them to receive the amounts. If for GKVs and PKVs, the Transitory Rebate cannot be paid at an aggregate level to the GKV-Spitzenverband and to the PKV-Verband respectively, in the alternative, Aspen will pay the Transitory Rebate directly to the individual health insurance funds. vi. Aspen proposes to calculate the rebate allocation between the three main categories (GKVs, PKVs and Beihilfe) as follows (2018 data is being used for illustrative purposes, the latest available data will be used for the actual computations): a) In 2018, a total of 104 GKVs had an aggregate number of persons covered of 72.13 million and 42 PKVs (of which 35 provide comprehensive health insurance) an aggregate of 8.74 million. In addition, the two closed funds covered 0.65 million. This gives a total of insured persons of 81.52 million.

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	b) In its financial report for the year ended 31 December 2018 the PKV Association stated that the member base can be divided into those that receive financial support and those that don't and that the majority of those that do are civil servants and their family members via Beihilfe. In 2018 share of the members receiving financial support made up 50.3% of the total member base (49.8% in 2017). So, for the purposes of allocating the rebates, Aspen will assume that 50% of the members are partially funded by Beihilfe. The extent of funding by Beihilfe does vary between employers or states, but is broadly comparable and covers between 50% and 70% of their private health insurance costs depending on the status of the insured: o 50% for civil servants without children or with a child; o 70% for a non-working spouse; o 80% of the costs for medical treatment for own children of the civil servants; o The income of the insured does not exceed certain limits; o 70% for civil servants with two children and more; o 70% among pensioners. c) The amount of the PKV Transitory Rebate applicable to Beihilfe is based on the assumption that on average 60% of the cost of private medical insurance is covered by Beihilfe. This assumption coupled with the 50% of PKV members that are assumed to be funded in this way means that 30% of any rebate accrued to the PKVs is deemed to relate to the Beihilfe.
Fall-back Recipient	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 a Fall-back Recipient (as laid down in paragraph 9 of the Proposed Commitments), Aspen will, pursuant to paragraph 9 of the Proposed Commitments, pay any remainder amount to the following Fall-back Recipient: German Cancer Consortium (DKTK). 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 a Fall-back Recipient (as laid down in paragraph 9 of the Proposed Commitments), Aspen will, pursuant to paragraph 9 of the Proposed

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	Commitments, pay any remainder amount to the following Fall-back Recipient: Georg Speyer Haus. For individual patients who incurred a co-payment cost: After the expiry of 18 months from the date of the notification to patients, any unclaimed co-payment rebates will be allocated to the German Cancer Consortium (DKTK).

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 a Fall-back Recipient (as laid down in paragraph 9 of the Proposed Commitments), Aspen will, pursuant to paragraph 9 of the Proposed 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. 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 a Fall-back Recipient (as laid down in paragraph 9 of the Proposed Commitments), Aspen will, pursuant to paragraph 9 of the Proposed Commitments, pay any remainder amount to the following Fall-back Recipient: Landspitali - The National University Hospital of Iceland (Føroyskt – Landspítali).

12. 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 a Fall-back Recipient (as laid down in paragraph 9 of the Proposed Commitments), Aspen will, pursuant to paragraph 9 of the Proposed Commitments, pay any remainder amount to the following Fall-back Recipient: Precision Oncology Ireland.

13. 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 a Fall-back Recipient (as laid down in paragraph 9 of the Proposed Commitments), Aspen will, pursuant to paragraph 9 of the Proposed 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).

14. 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 a Fall-back Recipient (as laid down in paragraph 9 of the Proposed Commitments), Aspen will, pursuant to paragraph 9 of the Proposed Commitments, pay any remainder amount to the following Fall-back Recipient: National Cancer Institute (Nacionalinis vėžio institutas).

15. MALTA	
Appropriate Beneficiary	Aspen will pay the Transitory Rebate to the Ministry for Health (Ministeru għas-Saħħa) through the means of a payback/retrospective one-off 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 a Fall-back Recipient (as laid down in paragraph 9 of the Proposed Commitments), Aspen will, pursuant to paragraph 9 of the Proposed Commitments, pay any remainder amount to the following Fall-back Recipient: Sir Anthony Mamo Oncology Centre (Centru ta' l-Onkoloġija Sir Anthony Mamo).

16. NETHERLANDS	
Appropriate Beneficiary	Aspen will pay the Transitory Rebate to the 24 Health Insurance Companies (Zorgverzekeraars). See Table 1 below.
Methodology	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 based on the allocation set out below. 1. Aspen will calculate the value of the Transitory Rebate per Product based on Aspen's internal and LSP sales data. Aspen will contact Zorgverzekeraars Nederland (ZN), the umbrella organization of health insurers, in order to establish if specific reimbursement volumes are available and if so, to work out the logistics of pay-backs. 2. Aspen will allocate the rebate proportionately between the health insurers using the volume data received from ZN. 3. Aspen will pay the health insurers according to a methodology to be agreed with ZN. To the extent that sufficient volume data is not available to enable the above methodology to be followed, Aspen will agree an alternative methodology with ZN, for instance by relying on the rebates paid to the insurers in proportion to their membership as a share of the insured population.
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 a Fall-back Recipient (as laid down in paragraph 9 of the Proposed Commitments), Aspen will, pursuant to paragraph 9 of the Proposed Commitments, pay any remainder amount to the following Fall-back Recipient: the Netherlands Cancer Institute (Nederlands Kanker Instituut) (NKI).

17. NORWAY	
Appropriate Beneficiary	Aspen will pay the Transitory Rebate to the Regional Health Authorities (Regionalt helseforetak) (RHF). See Table 1 below.
Methodology	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. 1. Aspen will calculate the Transitory Rebate payable by each RHF on the basis of LSP and wholesaler by Product and by Region sales data. 2. Aspen will use the combined sales per Region to proportionately allocate the rebates for special license import Products, to the extent that regional sales data is not available for a particular Product. 3. Where regions have combined for the purposes of tenders or other purchases, Aspen will allocate the Transitory Rebate between the relevant RHFs 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 a Fall-back Recipient (as laid down in paragraph 9 of the Proposed Commitments), Aspen will, pursuant to paragraph 9 of the Proposed Commitments, pay any remainder amount to the following Fall-back Recipient: Institute for Cancer Research, Oslo University Hospitals (Institutt for Kreftforskning, Oslo Universitetssykehus).

18. 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 a Fall-back Recipient (as laid down in paragraph 9 of the Proposed Commitments), Aspen will, pursuant to paragraph 9 of the Proposed Commitments, pay any remainder amount to the following Fall-back Recipient: Maria Sklodowska-Curie National Research Institute Of Oncology (Narodowy Instytut Onkologii im. Marii Skłodowskiej-Curie – Państwowy Instytut Badawczy).

19. PORTUGAL	
Appropriate Beneficiary	Aspen will pay the Transitory Rebate to hospitals.
Methodology	As there are several hospitals in Portugal ultimately paying or reimbursing the Products' purchase price, Aspen will pay the Transitory Rebate to the relevant hospitals based on the allocation set out below. 1. Based on Aspen's internal and distributor 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 distributor 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 a Fall-back Recipient (as laid down in paragraph 9 of the Proposed Commitments), Aspen will, pursuant to paragraph 9 of the Proposed 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.

20. ROMANIA	
Appropriate Beneficiary	Aspen will pay the Transitory Rebate to the Romanian National Health Insurance House (NHIH) (Casa Naţională de Asigurări de Sănătate) (CNAS) in the form of a donation to NHIH / 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 a Fall-back Recipient (as laid down in paragraph 9 of the Proposed Commitments), Aspen will, pursuant to paragraph 9 of the Proposed Commitments, pay any remainder amount to the following Fall-back Recipient: Oncology Institute „Prof. Dr I. Chiricuta" Cluj-Napoca.

21. SLOVAKIA	
Appropriate Beneficiary	Aspen will pay the Transitory Rebate to the three Public Health Insurance Funds (PHIFs) (Verejné zdravotné poisťovne). See Table 1 below.
Methodology	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. 1. Aspen will calculate the value of the Transitory Rebate based on available sales data. 2. Aspen will allocate and pay the Transitory Rebate to the PHIFs in proportion to their membership. The allocation will be based on the following assumptions: 1. each PHIF provides coverage for oncology treatment; and 2. each PHIF has the same per capita incidence of relevant types of cancer.
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 a Fall-back Recipient (as laid down in paragraph 9 of the Proposed Commitments), Aspen will, pursuant to paragraph 9 of the Proposed 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).

22. 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 a Fall-back Recipient (as laid down in paragraph 9 of the Proposed Commitments), Aspen will, pursuant to paragraph 9 of the Proposed Commitments, pay any remainder amount to the following Fall-back Recipient: Ljubljana Institute of Oncology (Onkološki inštitut Ljubljana).

23. 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), as well as the private healthcare insurers and, if applicable, the General Judicial Mutual Insurance Company (Mutualidad General Judicial-MUGEJU), and the General Spanish Civil Service Mutual Insurance Company (Mutualidad General de los Funcionarios).
Methodology	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. Aspen will pay the Transitory Rebate relating to public hospital sales to the Regions via an agreed mechanism. For private hospital sales Aspen will split the amount of Transitory Rebate between the Mutual Societies and the private health insurers. Aspen will use the following methodology: 1. Aspen will calculate the value of the Transitory Rebate per Product per customer based on its internal and distributor sales data. 2. Aspen will allocate the value of the Transitory Rebate for public and private hospitals as follows: a. ***Public hospitals*** – the Transitory Rebates will be aggregated by Region based on the location of the customer. Prior to the Transitory Rebates being paid, Aspen will agree a mechanism for the payment of the Transitory Rebate with the Regions. b. ***Private hospitals –*** prior to the Transitory Rebate becoming payable Aspen will consult with the Mutual Societies and the private health insurers in order to identify both an appropriate share of the Transitory Rebate as well as a methodology for its payment.
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 a Fall-back Recipient (as laid down in paragraph 9 of the Proposed Commitments), Aspen will, pursuant to paragraph 9 of the Proposed Commitments, pay any remainder amount to the following Fall-back Recipient: the Ministry of Health (Ministerio de Sanidad).

24. 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 1 below.
Methodology	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. Aspen will split the Transitory Rebate on the basis of in-patient (hospital) and out-patient sales. In particular: 1. Aspen will calculate the value of the Transitory Rebate per Product and pack based on Aspen's internal and LSP/wholesaler data; 2. Aspen will collect from the Dental and Pharmaceutical Benefits Agency (Tandvårds- och läkemedelsförmånsverket - TLV) or from Regions data to identify in-patient and out-patient sales; 3. Aspen will allocate the per pack Transitory Rebate to the regional hospital volumes and the total retail volumes in order to determine the total Transitory Rebate per region (for hospital sales) and per Product (for retail sales). In the absence of available data, this allocation of the Transitory Rebate will be based on the following assumptions: 1. Each regional government provides coverage for oncology treatment; 2. Each regional government has the same per capita incidence of relevant types of cancer; and 3. The hospital and retail channels have equal pricing.
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 a Fall-back Recipient (as laid down in paragraph 9 of the Proposed Commitments), Aspen will, pursuant to paragraph 9 of the Proposed Commitments, pay any remainder amount to the following Fall-back Recipient: Regionala Cancercentrum I Samverkan.

25. 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 a Fall-back Recipient (as laid down in paragraph 9 of the Proposed Commitments), Aspen will, pursuant to paragraph 9 of the Proposed Commitments, pay any remainder amount to the following Fall-back Recipient: UCH Macmillan Cancer Centre.

Table 1 – Appropriate Beneficiaries

Relevant Country	Appropriate Beneficiaries	
Austria	For the Social Health Insurance Funds (SHIFs), the Umbrella Organisation of Social Security Institution (UO-SSI) (Dachverband der Sozialversicherungsträger) (SV) 1. Österreichische Gesundheitskasse – ÖGK 2. Sozialversicherungsanstalt der Selbständigen – SVS 3. Versicherungsanstalt öffentlich Bediensteter, Eisenbahnen und Bergbau – BVAEB	Länder: 1. Vienna (Wien) 2. Lower Austria (Niederösterreich) 3. Upper Austria (Oberösterreich) 4. Styria (Steiermark) 5. Tyrol (Tirol) 6. Carinthia (Kärnten) 7. Salzburg 8. Voralberg 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) (НЗОК)	
Czech Republic	Seven Public Health Insurance Funds (Fondy veřejného zdravotního pojištění) (PHIFs) 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
Denmark	Six Regions (Regioner) 1. Færøerne	

Relevant Country	Appropriate Beneficiaries	
	2. Hovedstaden 3. Midtjylland 4. Nordjylland 5. Sjælland 6. Syddanmark	
Estonia	Estonian Health Insurance Fund (EHIF) (Eesti Haigekassa)	
Finland	21 Hospital districts (21 Sairaanhoitopiiri) 1. Södra Karelens social- och hälsovårdsdistrikt (Eksote) 2. Syd-Österbottens sjukvårdsdistrikt 3. Södra Savolax sjukvårdsdistrikt 4. Helsingfors och Nylands sjukvårdsdistrikt 5. Samkommunen för Östra Savolax sjukvårdsdistrikt, Sosteri 6. Kajanalands samkommun för social- och hälsovårdP 7. Centrala Tavastlands sjukvårdsdistrikt 8. Mellersta Österbottens samkommun för specialiserad sjukvård och grundservic 9. Mellersta Finlands sjukvårdsdistrik 10. Carea – Samkommunen för sjukvårds- och socialtjänster i Kymmenedalen 11. Lapplands sjukvårdsdistrikt 12. Länsi-Pohja sjukvårdsdistrikt 13. Birkalands sjukvårdsdistrikt 14. Samkommunen för sjukvårds- och socialtjänster i Norra Karelen 15. Norra Österbottens sjukvårdsdistrikt 16. Norra Savolax sjukvårdsdistrikt 17. Samkommunen för Päijät-Häme social- och hälsovård 18. Satakunta sjukvårdsdistrikt 19. Vasa sjukvårdsdistrikt 20. Egentliga Finlands sjukvårdsdistrikt 21. Ålands hälso- och sjukvård, ÅHS	Social Insurance Institution of Finland's (Kansaneläkelaitos) (KELA) health insurance fund
France	Health insurance system (Agence Centrale des Organismes de Securite Sociale) (ACOSS)	

Relevant Country	Appropriate Beneficiaries				
Germany	GKVs **(**Gesetzliche Krankenversicherungen) AOK Krankenkassen 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 Innungskrankenkassen 19. BIG direkt gesund 20. IKK Brandenburg und Berlin 21. IKK classic 22. IKK gesund plus 23. IKK Nord 24. IKK Südwest Betriebskrankenkassen	PKVs **(**Private Krankenversicherungen) 1. Allianz Private Krankenversicherung 2. Alte Oldenburger Krankenversicherung AG 3. ARAG Allgemeine Versicherungs-AG 4. Axa Krankenversicherung 5. Barmenia Krankenversicherung 6. Bayerische Beamtenkrankenkasse 7. Central Krankenversicherung 8. Concordia Krankenversicherung 9. Continentale Krankenversicherung 10. Debeka Krankenversicherung 11. DFV Deutsche Familienversicherung AG 12. Deutscher Ring 13. DEVK 14. die Bayerische 15. DKV Deutsche Krankenversicherung AG 16. ENVIVAS Krankenversicherung 17. ERGO Group AG 18. FREIE ARZT-UND MEDIZINKASSE der Berufsfeuerwehr und der Polizei	Beihilfe	Two Closed Funds affiliated to the PKV-Verband; Krankenversorgung der Bundesbahnbeamten (KVB) and Postbeamtenkrankenkasse (PBEAKK)	Individuals on the basis of co-payment

Relevant Country	Appropriate Beneficiaries				
	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) 56. BKK VDN	19. Gothaer Krankenversicherung 20. Hallesche Krankenversicherung auf Gegenseitigkeit 21. HanseMerkur 22. Inter Krankenversicherung 23. Krankenversorgung der Bundesbahnbeamten 24. Krankenunterstützungskasse der Berufsfeuerwehr Hannover (KUK) 25. LIGA Krankenversicherung katholischer Priester 26. LKH Landeskrankenhilfe 27. LVM Krankenversicherung 28. Mannheimer Krankenversicherung AG 29. Mecklenburgische Versicherungsgruppe 30. Münchener Verein 31. Nürnberger Krankenversicherung 32. ottonova Krankenversicherung AG 33. PAX-FAMILIENFÜRSORGE 34. Postbeamtenkrankenkasse 35. Provinzial Krankenversicherung Hannover AG (VGH) 36. R + V Krankenversicherung 37. Signal Iduna Krankenversicherung			

Relevant Country	Appropriate Beneficiaries				
	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 87. BKK KARL MAYER	38. SONO Krankenversicherung 39. ST. MARTINUS Priesterverein Rottenburg-Stuttgart 40. Süddeutsche Krankenversicherung 41. UKV Union Krankenversicherung 42. universa Krankenversicherung 43. Vigo Krankenversicherung 44. Württembergische Krankenversicherung			

Relevant Country	Appropriate Beneficiaries				
	88. Koenig & Bauer BKK 89. Krones 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				
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 Ligonių Kasa) (VLK)				
Malta	Ministry for Health (Ministeru għas-Saħħa)				
Netherlands	24 Health Insurance Companies (Zorgverzekeraars) divided into 11 groups: 1. ASR Nederland N.V.				

Relevant Country	Appropriate Beneficiaries
	2. Coöperatie Menzis U.A., including: a. Anderzorg NV 3. Zilveren Kruis Zorgverzekeringen N.V., including: 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: a. OHRA Zlektekosten b. OHRA Zorgverzekeringen c. Nationale-Nederlanden 5. OWM DSW Zorgverzekeraar U.A., including: 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: 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) 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 Naţională de Asigurări de Sănătate) (CNAS)	
Slovakia	Three Public Health Insurance Funds (PHIFs) (Verejné zdravotné poisťovne): 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	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) 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 (Estremadura)	Private hospital care: private healthcare insurance and, if applicable, the General Judicial Mutual Insurance Company (Mutualidad General Judicial-MUGEJU), the General Spanish Civil Service Mutual Insurance Company (Mutualidad General de los Funcionarios)

Relevant Country	Appropriate Beneficiaries	
Sweden	In-patient use: 21 regional governments (County Council, County, Region) (Inpatient användning: 21 regionala regeringar (landsting, län, region)) 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 Norbotten 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 Östergötlande	Out-patient use: national government (Öppenvård: nationell regering)
United Kingdom	National Health Service (NHS)	

2. Residual fall-back recipient

10) 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.

11) Any amount of the Transitory Rebate that has not been allocated to the Appropriate Beneficiaries pursuant to paragraph 9 i) to v) of the Proposed Commitments, will be paid to the following residual fall-back recipient: ESMO.

Case AT. 40394 – Aspen

Annex 2

AT.40394 – Aspen

Annex 2 – Identification and allocation of indirect costs

This Annex 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 Proposed Commitments. In particular, this Annex 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 Products[3] 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, Medial 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 Septrin, 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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Annex 3

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Annex 3 – Gross and List Prices for Products with List Prices Commercialised in FY2019

Relevant Country[1]	Reduced Prices[2]	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	-	-	-	-	-	-	-	-	-
	Listed WSP	-	€ 40.99	-	-	€ 36.75	-	-	-	-
	Listed PSP	-	€ 57.54	-	-	€ 51.83	-	-	-	-
	Gross Price	-	[€ 51.76 –	-	-	[€ 38.70 –	-	-	[€ 76.95 –	[€ 36.00 –

[1] For confidentiality reasons, Gross Price levels have as appropriate been replaced by ranges.

[2] "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[1]	Reduced Prices[2]	Alkeran IV	Alkeran tab 25	Alkeran tab 50	Lanvis 25	Leukeran 25	Leukeran 50	Myleran 25	Myleran 100	Purinethol 25
			56]			42]			84]	39]
Estonia[3]	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[4]	-	-	-	-	-	-	-	-	-
	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]
	Listed MSP[5]	-	-	-	-	-	-	-	-	-
	Listed WSP	€ 42.35	€ 52.84	-	-	€ 28.52	-	-	-	€ 14.48

[3] The "MSP" is effectively Aspen's Gross Price; it is not a listed price in this Member State.

[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[1]	Reduced Prices[2]	Alkeran IV	Alkeran tab 25	Alkeran tab 50	Lanvis 25	Leukeran 25	Leukeran 50	Myleran 25	Myleran 100	Purinethol 25
	Listed PSP	-	-	-	-		-	-	-	-
Latvia[6]	**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[7]	-	-	-	-	-	-	-	-	-
	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	-	-
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

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.

Relevant Country[1]	Reduced Prices[2]	Alkeran IV	Alkeran tab 25	Alkeran tab 50	Lanvis 25	Leukeran 25	Leukeran 50	Myleran 25	Myleran 100	Purinethol 25
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[8]	-	-	-	-	-	-			
	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	-	-	-	-	-	-	-	-	-

[8] The "MSP" reflects also the distributor margin; the "MSP" is not a listed price in this Member State.

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Annex 4

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Annex 4 – Regulatory Authorities

Relevant Country	Regulatory Authority
Austria	Price 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 – НСЦРЛП)
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	Social Insurance Institution of Finland (Kansaneläkelaitos – KELA)
France	Comité économique des produits de santé (CEPS)
Germany	Federal Ministry of Health (Bundesministerium fur Gesundheit – BMG)[1]
Iceland	Icelandic Medicine Pricing and Reimbursement Committee (Lyfjagreiðslunefnd)
Ireland	Health Service Executive (HSE) (Feidhmeannacht na Seirbhíse Sláinte) & Irish Pharmaceutical Healthcare Association (IPHA)
Latvia	National Health Service (Nacionālā veselības dienesta – NVD)
Lithuania	State Health Insurance Fund (Valstybinė Ligonių 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 product
Poland	Ministry of Health (Ministerstwo Zdrowia – MZ)
Romania	The National Health Insurance House of Romania (Casa Naţională de Asigurări de Sănătate – CNAS)
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)
United Kingdom	Department of Health and Social Care (DHSC)

[1] Aspen will update the prices with Informationsstelle fur Arzneispezialitaten Gmbh (IFA).

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Annex 5

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Annex 5 – Gross Prices for Products without List Prices Commercialised in FY2019

Relevant Country[1]	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				-	-	-	-	-
Portugal[2]	-	[€ 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] For confidentiality reasons, Gross Price levels have as appropriate been replaced by ranges.

[2] The listed Products in Spain and Portugal, including Products for which Aspen holds marketing authorizations, are sold using foreign packs at Gross Prices.