

## **A480 – PRICE INCREASE OF ASPEN’S DRUGS**

*Measure No. 26185*

THE ITALIAN COMPETITION AUTHORITY

IN THE HEARING held on 29 September 2016;

HAVING HEARD Rapporteur Gabriella Muscolo;

HAVING REGARD to Law No. 287 of 10 October 1990;

HAVING REGARD to article 102 of the Treaty on the Functioning of the European Union;

HAVING REGARD to Council Regulation (EC) No. 1/2003 of 16 December 2002;

HAVING REGARD to the Commission Notice on cooperation within the Network of Competition Authorities of 27 April 2004;

HAVING REGARD to D.P.R. No. 217 of 30 April 1998;

HAVING REGARD to its measure No. 25186 of 19 November 2014, through which it launched an investigation, pursuant to article 14 of Law No. 287/90, against Aspen Pharma Trading Ltd. and Aspen Italia S.r.l. so as to verify said undertakings’ possible anti-competitive behaviours infringing article 102 of the TFEU;

HAVING REGARD to its measures of 11 February 2015 and 13 May 2015, through which the investigation was extended against Aspen Pharma Ireland Ltd. and Aspen Pharmacare Holdings Ltd., respectively;

HAVING REGARD to the association Altroconsumo’s request to participate in the investigation, pursuant to article 7, paragraph 1, of D.P.R. No. 217 of 30 April 1998;

HAVING REGARD to the Communication on the Results of the Investigation (Comunicazione delle Risultanze Istruttorie - CRI) and on the closing of the preliminary phase for acquiring probative elements sent to the Parties on 30 October 2015;

HAVING REGARD to its measure of 11 November 2015, through which the deadline of the investigation was extended to 30 March 2016;

HAVING REGARD to the final brief submitted by Aspen Pharma Trading Ltd. and Aspen Italia S.r.l., Aspen Pharma Ireland Ltd. and Aspen Pharmacare Holdings Ltd., received on 2 February 2016, as well as the one submitted by Altroconsumo, received on 4 February 2016;

HAVING HEARD the Parties on 9 February 2016;

HAVING REGARD to its measure of 9 February 2016, through which the Authority resolved for the Foodstuffs and Transport Directorate – Competition to clarify the charges notified in the Communication on the Results of the Investigation with reference to an alleged abuse of dominant position pursuant to article 102, letter a), of the TFEU, sending a new communication to the Parties and ordering a new extension of the deadline for closing the inquiry;

HAVING REGARD to its measure No. 25933 of 17 March 2016, through which the Authority resolved to substitute the person in charge of the investigation;

HAVING REGARD to the Communication on the Results of the Investigation sent to the Parties on 22 April 2016;

HAVING REGARD to its measure No. 26002 of 4 May 2016, through which the Authority extended the deadline for closing the investigation to 30 September 2016;

HAVING REGARD to the final brief submitted by Aspen Pharma Trading Ltd. and Aspen Italia S.r.l., Aspen Pharma Ireland Ltd. and Aspen Pharmacare Holdings Ltd., received on 28 June 2016, as well as the one submitted by Altroconsumo, received on 30 June 2016;

HAVING HEARD the representatives of Aspen Pharma Trading Ltd., Aspen Italia S.r.l., Aspen Pharma Ireland Ltd., Aspen Pharmacare Holdings Ltd. and Altroconsumo in the final hearing held on 5 July 2016;

HAVING REGARD to the acts of the inquiry and the documentation collected during the investigation;

WHEREAS:

### **I. PRELIMINARY REMARKS**

1. On the basis of news referring about a significant price increase in 2014 of several anticancer drugs commercialised in Italy by the undertaking Aspen Pharma Trading Limited (hereafter, also “APTL”), and taking into consideration information received on 19 November 2014 from the Italian Medicines Agency (Agenzia Italiana del Farmaco, hereafter also “AIFA” or “the Regulator”), the Authority launched an investigation against APTL and Aspen Italia S.r.l. (hereafter, also “AI”) so as to verify an alleged infringement of article 102 of the Treaty on the Functioning of the European Union (hereafter, TFEU).

## II. THE INVESTIGATION

### II.1. NEWS OF PRICE INCREASES

2. In July 2014 the Authority was reached by the news of price increases involving the following specialty drugs (hereafter, also "Aspen's drugs") owned by APTL and belonging to reimbursement classes A and H (that is, at the expense of the National Healthcare System, "Servizio Sanitario Nazionale", hereafter also "SSN"):

- Leukeran 2 mg – 25 tablets (chlorambucil);
- Alkeran 50 mg/10 mg powder and solvent for solution for injection – 1 vial (melphalan);
- Alkeran 2 mg – 25 tablets (melphalan);
- Purinethol 50 mg – 25 tablets (mercaptopurine);
- Tioguanine 40 mg – 25 tablets (tioguanine).

3. On 17 March 2014, following the outcomes of a negotiation opened by APTL, AIFA decided to allow an extremely high price increase for the mentioned drugs, with percentages ranging between 300% and 1,500% of the initial prices.

4. The news of said increase was given also by the consumers association Altroconsumo upon an investigation launched into the so-called "drug disappearance" phenomenon that involved the pharmaceutical distribution network.<sup>1</sup>

**Table n. 1: Old and new prices of Aspen's drugs in Italy**

	<b>Vecchio prezzo ex factory*</b>	<b>Nuovo prezzo ex factory</b>	<b>Vecchio prezzo al pubblico</b>	<b>Nuovo prezzo al pubblico</b>	<b>delta % prezzo al pubblico</b>
<b>Alkeran</b>	€ 3,51	€ 57,62	€ 5,80	€ 95,10	1540%
<b>Alkeran inj</b>	€ 31,46	€ 149,87	€ 69,21	€ 247,35	257%
<b>Leukeran</b>	€ 4,54	€ 57,53	€ 7,50	€ 94,95	1166%
<b>Purinethol</b>	€ 10,19	€ 57,62	€ 16,82	€ 95,10	465%
<b>Tioguanina</b>	€ 32,71	€ 132,96	€ 53,99	€ 219,44	306%

\*An *ex factory* or *ex fabrica* price refers to the price of a drug at the factory before adding percentages for the pharmaceutical distribution. Whereas, the price to the public is obtained by adding to the *ex factory* price the amounts envisaged for the remuneration of the subjects belonging to the distribution chain (wholesalers and pharmacists).

Data source: AIFA

### II.2. PRE-INVESTIGATION AND INVESTIGATION ACTIVITIES

5. In order to acquire useful elements for understanding the price increase phenomenon of the drugs listed in Table n. 1, on 30 July 2014 the Directorate sent AIFA a request for information. The latter provided a first reply on 8 September 2014, further integrated with following communications on 9 and 22 October 2014 and, lastly, on 11 November 2014.

6. In the light of the elements acquired during the preliminary phase mentioned above, and pursuant to article 102 of the TFEU and article 14 of Law No. 287/1990, on 19 November 2014 the Authority launched an investigation against APTL and AI so as to verify whether the mentioned undertakings were carrying out behaviours restricting competition.

7. On 27 November 2014 inspections were carried out at AI's and APTL's premises, as well as at the premises of Aspen Pharma Ireland Limited (hereafter, also "APIL"), Laboratorio Farmacologico Milanese S.r.l. (hereafter, also "LFM") and GlaxoSmithKline S.p.A. (hereafter, also "GSK"). During said inspections, a vast documentation was collected referring to the object of the inquiry hereof.

The inspections at the premises of the foreign undertakings APTL and APIL were carried out by the Irish Competition Authority (Competition and Consumer Protection Commission; hereafter, also CCPC) implementing a cooperation request submitted pursuant to article 22 of Regulation No. 1/2003.<sup>2</sup> The documentation gathered by the CCPC during its inspections was sent to the Authority, pursuant to article 12 of the mentioned Regulation, on 1<sup>st</sup> December 2014 and 19 January 2015. The documentation received was filed by the Authority in its inquiry report.<sup>3</sup>

<sup>1</sup> [On 10 September 2014, Altroconsumo informed the Ministry of Health and AIFA concerning the outcomes of an investigation carried out on the basis of its members' reports that notified the association of the disappearance from the market of a series of drugs, among which also the specialty drugs object of the proceedings hereof. In its note, Altroconsumo highlighted that the disappearance of many drugs from the distribution network was the sign of a very significant increase in drug prices. AIFA forwarded said note to the Authority on 8 October 2014 (cf. doc. 4 of the inquiry report).]

<sup>2</sup> [Doc. 19.]

<sup>3</sup> [Cf. doc. 20 and doc. 44.]

8. On 9 December 2014, the consumers association Altroconsumo submitted a request to participate in the investigation, pursuant to article 7, paragraph 1, of D.P.R. No. 217/98. The request was accepted on 23 December 2014.<sup>4</sup>

9. With resolution of 11 February 2015, the Authority extended the investigation against the Irish undertaking APIL, on the basis of the documentation collected during inspections, which indicated the involvement of the mentioned undertaking in the conducts identified in the preliminary phase.

10. With resolution of 13 May 2015, the Authority further extended the investigation against the South-African parent company Aspen Pharmacare Holdings Limited (APHL), on the basis of the documentation collected and of the elements acquired during the Party's hearings concerning the holding's involvement in the facts charged with reference to the proceedings hereof.

11. During the inquiry, hearings were carried out with representatives from: AIFA (13 April 2015), the Aspen group (7 May 2015) and GIMEMA Foundation (13 May 2015).<sup>5</sup>

12. During the investigation, the Directorate submitted various requests for information to AIFA, the Ministry of Health and Aspen.<sup>6</sup>

13. The Party submitted its brief on 20 July 2015.<sup>7</sup>

14. On 30 October 2015, the Communication on the Results of the Investigation (Comunicazione delle Risultanze Istruttorie, hereafter CRI) was sent to the Parties, following the Authority's resolution of 28 October 2015.

15. The deadline for closing the inquiry was extended to 30 March 2016, with resolution of 11 November 2015, following a request submitted by Aspen.

Aspen filed its final brief on 2 February 2016. Altroconsumo produced its final brief on 3 February 2016.

16. On 9 February 2016 the Parties were heard before the Board. In said context, following Aspen's observations formulated during the hearing and on the basis of its brief, the Authority resolved for the Foodstuffs and Transport Directorate to clarify the charges notified against the Party with reference to an alleged abuse of dominant position infringing article 102, lett. a), of the TFEU, sending a new CRI to the Parties involved and ordering the deadline for the closing of the investigation to be extended.

On 11 February 2016 the Parties were notified of the Authority's resolution (resolved on 9 February 2016 during its extraordinary meeting), containing the new final deadline for closing the inquiry, set for 30 June 2016.

17. On 17 March 2016 the Authority resolved to substitute the person in charge of the investigation, as notified to the Parties on 31 March 2016.

18. On 22 April 2016 the Parties received the new CRI, as resolved by the Authority on 19 April 2016.

19. The deadline for closing the investigation was extended to 30 September 2016 with resolution of 4 May 2016, following the Party's request.

20. Aspen submitted its final brief on 28 June 2016, and Altroconsumo on 30 June 2016.

21. The Parties were heard before the Board in the final hearing held on 5 July 2016.

22. During the proceedings, the Parties and the intervener were repeatedly granted access to the acts filed, and specifically: the Aspen group on 13 January, 12 February, 24 April, 19 June 2015; 22 January, 5 February and 3 May 2016; Altroconsumo on 21 May and 19 November 2015; 5 February, 26 May and 4 July 2016.<sup>8</sup>

### **II.3. THE PARTIES**

#### **II.3.1 The Aspen Group**

23. Aspen Pharma Trading Limited (APTL), with registered office in Dublin, is a company of the South-African Aspen group, leader in the production and distribution of generic drugs and distributor of trademark drugs.

The group has been present in Europe since 2009, following an operation concluded at global level in which it purchased from GSK the right to commercialise an anticancer drug package (called within the company "Cosmos"

---

<sup>4</sup> [Cf. doc. 25 and doc. 35.]

<sup>5</sup> [Cf. doc. 84, doc. 94 and doc. 97. The GIMEMA Foundation (Gruppo Italiano Malattie Ematologiche dell'Adulto) is a non-profit organisation for clinical research in the haematological field, which acquired its current legal form in 1999. GIMEMA was created under the impulse of two renown haematologists, prof. Mandelli and prof. Tura, who – with the aim to maximise research results - grouped 9 Italian haematological centres in order to define shared protocols. GIMEMA's main purpose is to define aims and protocols for clinical research and gather related data. Over the years, 150 Italian haematological centres have joined the foundation. Owing to its organisational structure and its founding members' prestige, GIMEMA has been able to become strongly independent from pharmaceutical companies.]

<sup>6</sup> [Cf. documents 1, 81, 98, 108, 115.]

<sup>7</sup> [Cf. doc. 121 and annexes.]

<sup>8</sup> [Cf. documents 42, 91, 96, 117, 145, 157, 169, 174, 175.]

drugs).<sup>9</sup> The agreement was signed between Aspen Global Incorporated (hereafter, also "AGI") belonging to the Aspen group, and GSK.<sup>\*10</sup> However, the marketing authorisation (MA) for the European markets is held by APTL.

24. APTL's social capital is entirely held by the South-African parent company Aspen Pharmacare Holdings Limited (hereafter, also "APHL"), through AGI.<sup>11</sup>

25. Aspen Italia S.r.l. (AI) - in the Register of Companies since 21 June 2013 - has been active since September 2014, with registered office in Rome and an operational office in Verona. The undertaking is controlled entirely by AGI, which in turn is controlled by the South-African holding APHL.

26. Aspen Pharma Ireland Limited (APIL), with registered office in Dublin, is an undertaking under Irish law controlled by the South-African holding APHL through AGI.<sup>12</sup>

27. Aspen Pharmacare Holdings Limited (APHL) is the holding of the multinational pharmaceutical group, with registered office in Durban, South Africa.

28. APHL is the undertaking in charge of defining pricing strategies for Aspen's products in Europe. APIL's role is to implement said strategies in the European Union's markets. APIL's General Manager is [Mr. A], who at the moment of the negotiation acted as APIL's General Manager and APTL's Director.<sup>13</sup> In the period relevant for the negotiation, the South-African person of reference for the negotiation and pricing strategies was [Mr. B], acting as APHL's Group Commercial Executive.

In Europe, APIL is in charge of the supply chain management, under the control of the South-African holding. The person in charge of said function in APIL is [Mr. C] (Head of European Supply Chain), assisted by [Mr. D] (Supply Chain Manager for Italy).<sup>14</sup>

29. In Italy, AI is APIL's broker for Aspen's products sold according to the so-called "consignment model" (drugs transferred on consignment, whose property remains the transferor's).<sup>15</sup> AI's General Manager is [Mr. E], former employee of GSK in Italy. Mr. E was one of the subjects appointed by the Aspen group to manage the negotiation with AIFA.

However, the products object of the inquiry are excluded from the brokering contract between AI and APIL because distributed in Italy through the so-called "buy and sell model," that is through a distributor that purchases the property of the drug stock.

Laboratorio Farmacologico Milanese (LFM) is Aspen's sole distributor for the drugs under exam in the Italian market. The invoices for the mentioned products are issued to the distributor LFM by a different body of the group, namely the undertaking Aspen Healthcare (AH), with registered office in Dubai.<sup>16</sup>

APTL holds the marketing authorisation (MA) of Aspen's drugs distributed in Europe.

30. The production of Aspen's drugs in Europe is realised for Aspen by third-party producers on the basis of a contractual relationship. In fact, Alkeran for injection is produced by GSK in Parma, while the other drugs object of the inquiry are produced by the German company Excella GmbH (hereafter, also "Excella"). Upon request, Aspen produced a copy of the contracts with Excella and GSK Parma.<sup>17</sup> On the basis of the contract between AGI and Excella - that is, the undertaking that produces for Aspen the products Purinethol, Tioguanine, Leukeran and Alkeran in tablets - it is possible to identify a decreasing trend in the production costs of said drugs from 2012 to 2016. In particular, considering what agreed upon contractually, the prices paid by Aspen to Excella show a negative annual variation comprised between [1-5] and [5-10]%.<sup>18</sup>

31. The Aspen group uses Bad Oldesloe's premises in Germany - purchased by Aspen in 2009 during the transaction with GSK - to stock the products destined to the European markets, including the products coming from Excella.<sup>18</sup>

---

<sup>9</sup> [The COSMOS drug package also includes - besides those object of the inquiry, namely Alkeran, Leukeran, Purinethol and Tioguanine (called Lanvis in many national markets) - the drug Myleran and other anticancer drugs, which however are not commercialised in Italy. Hereafter, the term Cosmos will refer only to Aspen's products object of the proceedings hereof.]

\* [In this version some data have been omitted, as deemed confidential or classified.]

<sup>10</sup> [Aspen concluded the transaction paying an amount equal to about [300-400] million U.S. dollars. Part of the payment was regulated in liquidity and the remaining part through a transfer of an equity stake corresponding to about [15-20]% of Aspen's capital. The operation was not valued at community level because below threshold. Cf. doc. 97.]

<sup>11</sup> [Cf. doc. 97 page 2 and doc. 106, annex 1.]

<sup>12</sup> [Cf. doc. 106, annex 1.]

<sup>13</sup> [Cf. doc. 44 and doc. 97.]

<sup>14</sup> [Cf. doc. 20.2.]

<sup>15</sup> [Cf. doc. 97.]

<sup>16</sup> [Also this company is entirely controlled by the holding APHL (cf. doc. 106, annex 1). As specified by Aspen in its final brief (doc. 213, § 199), due to the "buy and sell" model, the profits deriving from the sales of Cosmos products in Italy are registered at central level by Aspen Healthcare, a company of the group with registered office in Dubai, and do not "transit" through Aspen's European companies.]

<sup>17</sup> [Doc. 116, annexes from 1 to 6.]

<sup>18</sup> [Cf. doc. 97.]

32. Said products do not require any investments in medical-scientific promotion in order to be commercialised since they have been used for many years now, as confirmed by GIMEMA's haematologists (cf. *infra*, § 70) and by a due diligence document drawn up by GSK.<sup>19</sup>

33. For the purposes of the inquiry, and on the basis of what mentioned above concerning:

i) the involvement of the South-African holding (APHL) in defining drug prices and negotiation strategies;

ii) the turnover related to Cosmos drugs in the Italian market ascribed to a company of the group controlled directly by APHL;<sup>20</sup>

iii) the involvement of undertakings APIL, APTL and AI in the conducts under exam

the Aspen group is deemed jointly liable of the conduct under exam. Therefore, the behaviours examined hereon will refer to the "Aspen group" in its whole (also only "Aspen" or "the Party"), unless reference is made to specific conducts directly ascribable to single undertakings within the group.

34. Aspen's turnover at global level in fiscal year from 1<sup>st</sup> July 2015 to 30 June 2016 was equal to € 2,212,500,000.<sup>21</sup> In the same fiscal year, Aspen's total turnover for selling Cosmos products in Italy was equal to € [5-10] million Euros.

### II.3.2 Intervener

35. Altroconsumo is a consumers association listed among the most representative consumers associations considered by the Ministry of Economic Development.

## III. THE NORMATIVE-REGULATORY FRAMEWORK

### III.1. DRUG CLASSES BASED ON THE REIMBURSEMENT FROM THE NATIONAL HEALTHCARE SYSTEM

36. Human drugs are classified on the basis of their reimbursement system. Therefore, the drugs in commerce are distinguished depending on the subject bearing related expenses, namely the SSN or patients.

37. Pursuant to article 8, paragraphs 10 and 14, of Law No. 537/1993 and following amendments and integrations, the reimbursement classes are as follows:

a) Class A: essential products and products for chronic diseases, fully reimbursed by the SSN.<sup>22</sup> These drugs are supplied by territorial pharmacies or public healthcare structures (direct distribution);

b) Class H: products for hospital use, reimbursed by the SSN, used in hospitals or healthcare structures;

c) Class C: products at patients' total expense. Within Class C there is a further distinction between drugs that require medical prescription and those that do not require prescription; the latter category is then distinguished between drugs for slight illnesses and that can be advertised to the public (OTC, the so-called Class C-*bis*) and those that cannot be advertised to the public (SOP – "Senza Obbligo di Prescrizione", that is without prescription obligation).

38. Drugs belonging to Class A and Class H are totally reimbursed by the SSN when covered by patent protection or however lacking generic or equivalent drugs in commerce. For off-patent drugs belonging to Class A – be they off-patent originator drugs or their generics – the SSN reimburses the lowest price among those of the equivalent drugs present on the market (the so-called price of reference).

39. The prices of drugs belonging to Class C are freely set by producers and fully paid by patients. AIFA monitors the prices of Class C drugs with obligation of medical prescription, as they can be increased only every two years (odd years) and said increases cannot be above planned inflation; whereas, the prices of drugs without obligation of medical prescription are freely established by producers.

40. In order to establish prices to the public of drugs belonging to any of the reimbursement classes, VAT and the amounts owed to wholesalers and pharmacists, as established by law, are added to the *ex fabrica* value (also called *ex factory price*).

### III.2. DRUG CLASSIFICATION PROCEDURE AND PRICE NEGOTIATION OF DRUGS SUBJECT TO REIMBURSEMENT

41. D.L. No. 158/2012 (the so-called Decreto Balduzzi), converted with amendments in Law No. 189/2012, modified the procedures regulating drug marketing authorisation and classification, providing for the possibility to submit classification requests and price definitions only after the MA has been issued.<sup>23</sup> Hence, Decreto Balduzzi made a

---

<sup>19</sup> [The mentioned document dates back to when the drugs were transferred to Aspen, and states expressly - for each single Cosmos product - that no investment had been made for promotion in the previous three years (and no changes were envisaged concerning the reimbursement regime or the price list): "The product is not actively promoted [...] No sales force promotion for the last 3 years [...] No promotion by any third party...No anticipated market change [...] No change to list price or reimbursement planned/anticipated" (Doc. 44.2, p. 2, 7, 9 and 22).]

<sup>20</sup> [Cf., by way of example, documents 20.17 B.116 and 20.17 B.133. ]

<sup>21</sup> [Doc. 227 and doc. 229.]

<sup>22</sup> [With the exception of the Regions' possibility to participate in the expense through the so-called tickets.]

<sup>23</sup> [The Marketing Authorisation (MA) of a drug is issued by AIFA on the basis of a long scientific-administrative procedure made of various study and experimentation phases. The MA and the Summary of Product Characteristics (hereafter, also "SPC"), annexed to the MA, provide drug dosage and therapeutic indications. ]

distinction between the marketing authorisation phase and the classification phase of a drug, which used to be carried out within the same procedure. Pursuant to article 12 of Decreto Balduzzi “[...]for a drug to be classified among those distributable by the National Healthcare System, pharmaceutical companies can submit a request to AIFA only after obtaining the marketing authorisation for said drug [...]”.

Pursuant to the same article, drugs that obtain marketing authorisation are automatically classified in a specific category for drugs not yet assessed as regards reimbursement, called “non-negotiated” Class C. The mentioned class is distinguished from the traditional ones, as it is a temporary classification until companies submit request for a different classification, and the reimbursement procedure is thus perfected.<sup>24</sup>

42. Pursuant to article 48, paragraph 33, of Law No. 326/2003 (AIFA’s institutive regulation), drug prices reimbursed by the State (Class A and Class H) are defined through a negotiation procedure between the company and AIFA, according to criteria defined in CIPE Resolution No. 3/2001 (CIPE: Comitato Interministeriale per la Programmazione Economica – Intra-Ministerial Committee for Economic Planning). Said Resolution sets the criteria for negotiating drug prices as well as negotiation procedures, establishing the obligations of both the company and the administration.<sup>25</sup>

43. Article 3 of CIPE Resolution provides for the company to submit a request for class reimbursement assignation and price negotiation, together with specific documentation proving:

- a favourable cost-effectiveness relationship, should the new drug provide prevention or treatment of pathologies for which there is no effective therapy;
- a favourable cost-effectiveness relationship, should the new drug prove to be better in the prevention or treatment of pathologies compared to other existing drugs;
- a more favourable cost-effectiveness relationship compared to drugs already on the market;
- data concerning economic and drug-economic factors.

44. In the negotiation procedure for establishing drug prices, AIFA is supported by the Technical Scientific Committee (Commissione Tecnico Scientifica - hereafter, also CTS) and the Pricing and Reimbursement Committee (Comitato Prezzi e Rimobrsio - hereafter, also CPR). It also makes use of data on drug consumption and expenditure provided by the National Observatory on the Use of Medicines (OsMed) and by experts from the National Institute for Healthcare (Istituto Superiore di Sanità). The negotiation procedure concludes with an actual contractual agreement between the pharmaceutical company and AIFA, with a 24 month validity renewed each time for another 24 months, unless one of the parties sends to the other a proposal to modify the agreement, at least 90 days before each expiry.

45. On the basis of article 5 of the Resolution, “*In order to have access to the negotiation, the company must submit specific request to the Ministry of Health [now AIFA] with documentation as mentioned in the annexed dossier.*” In fact, besides clinical, therapeutic and pharmacological information on the drug, the dossier annexed to the Resolution requires for the company to submit a series of economic and market data on which to base the determination of prices.

According to what provided by the “*Guidelines for submitting request for drug classification and pricing*” dated 17 January 2014 (the so-called Guidelines), published on AIFA’s website, companies submitting request for Class C must provide the information required from point No. 1 to No. 7 of the dossier annexed to the Resolution, while it is not necessary to submit the information mentioned under point 8, concerning costs.<sup>26</sup>

46. With particular regard to price definition, article 6 of CIPE Resolution establishes as follows: “*During the negotiation for price definition, both the company and the administration shall submit their proposals accompanied by adequate economic assessments of the product and of the industrial context (with reference to investments in*

---

<sup>24</sup> [Cf. doc. 112, pages 6-7.]

<sup>25</sup> [The competent administration identified by CIPE Resolution No. 3/2001 is the Ministry of Health, whose responsibility to establish drug prices was transferred to AIFA by the mentioned Law No. 326/2003.]

<sup>26</sup> [Points from No. 1 to No. 7 identify the drug’s clinical, therapeutic and scientific information:

1. Summarised aspects of the drug (title page) [...] 2. Drug characteristics and therapeutic framework [...] 3. Drug therapeutic indications [...] Drug position in therapy [...] 5. Clinical studies supporting the effectiveness and reimbursement of the product 6. Pharmacovigilance data of the Product 7. Other EU Countries in which the drug is commercialised.

Point 8 of the dossier identifies information related to costs borne for developing and producing the drug, necessary to support the price proposal:

“... 8.1 Cost of single packages

8.2 Cost per mg of active ingredient of the single packages

8.3 Cost per dosage unit of the single packages

8.4. Cost per DDD

8.5. Cost per therapy cycle with reference to the indications (if more than one)

8.6. Cost of drugs with documented similarities or clinical/therapeutic equivalences

8.7. Predictable number of individuals subject to the treatment in a year

8.8. Total market of the specific therapeutic sector (millions of Lira)

8.9. Market share/year of the product during the first three years of reimbursement (including sales of possible patents)

8.10. Other economic measures proposed by the Company for the benefit of the SSN (discounts, interventions on the prices of other specialty drugs of the same Company)

8.11. Investments in research and development carried out by the proposing company in Italy in the last three years (millions of Lira)

8.11. A in experimental research

8.11. B in clinical research

8.12. Production investments carried out in Italy by the proposing company in the last three years (millions of Lira).”]

production, research and development, and export), as well as evaluations concerning the market and competition in which the product is placed. The negotiation procedure shall conclude when the parties enter into a price definition agreement [...] Should an agreement on the price not be reached, the product shall be listed in Class C as mentioned under paragraph 10, of article 8, of Law No. 537 of 24 December 1993." [emphasis added].

As clarified by AIFA, the mentioned measure is applied in case the parties do not reach an agreement during a first drug price negotiation, as well as in case of price renegotiation.<sup>27</sup>

47. If the product is already commercialised in other countries, the request submitted by the company must also be accompanied by data concerning the prices, consumptions and reimbursement conditions in force abroad, which the administration can keep into account in determining the reimbursement class and in defining the price.<sup>28</sup> This measure stems from a system for establishing Class A drug prices in force until 2003, which referred to the so-called European Average Drug Prices (Prezzo Medio Europeo - PME).<sup>29</sup>

48. The first price determination of a drug introduced on the market for the first time and, in particular, of an innovative drug under patent protection, keeps into account Research and Development (R&D) costs borne by the company for realising the product.

Costs borne by a pharmaceutical company do not exhaust necessarily in direct investments in the research and development of the molecule or of the specialty drug under exam. On the contrary, they can include sunk costs related to failed attempts in new drug discoveries. Therefore, the price deriving from the first negotiation is characterised by the need to recover said expenses, essential for the innovation process.<sup>30</sup>

Secondly, given the estimated useful life of a product, its first price is established in such a way to make the investment borne by the company for its discovery, development and marketing remunerative, for the whole duration of the patent exclusiveness. At the end of said period, the fixed sunk costs initially borne by the company are to be considered fully amortized. Consequently, the price applied for the marketing of the drug is to cover only the marginal cost related to its production. Usually, but also for the case at hand, said costs tend to decrease over time.

49. As specified by the indications provided on AIFA's website (Request to review drug prices - annex 1) and as clarified by the Agency itself,<sup>31</sup> in case of requests to review an already approved price, AIFA evaluates said requests on the basis of the documentation submitted by the company motivating the request, taking into consideration the following conditions:

- lack of therapeutic substitutes within the Class;
- documented increase of production costs, with particular reference to raw material costs. Whereas, costs ascribable to the whole pharmaceutical production will not be taken into consideration, such as, for example, energy supply costs and personnel costs;
- documented increase of production costs due to regulatory measures aimed at improving the quality and safety of the specific drug.

50. AIFA specified that, before the entering into force of Law No. 537/1993, prices were established by referring to the accounting analysis of the various items of business costs associated to each single specialty drug and estimated through specific mathematical functions. Given the date of the first introduction on the Italian market of the drugs under exam, their first price determination took place according to the mentioned regime.<sup>32</sup>

### **III.3. EXTRAORDINARY REVIEW OF THE NATIONAL DRUG CODE (THE SO-CALLED DELISTING PROCEDURE)**

51. Article 11, paragraph 1, of Decreto Balduzzi appointed AIFA with the responsibility to carry out an extraordinary review of the National Drug Code (that is, the list of drugs reimbursed by the State), so as to evaluate the actual relevance of several drugs counting towards their possible inclusion in reimbursement Classes A and H.

52. In 2013 AIFA carried out the mentioned extraordinary review of the Drug Code identifying several drugs to be submitted to the evaluation of experts on the basis of specific criteria capable of identifying the likelihood of the therapeutic outdatedness of said drugs.

Some of the drugs object of the investigation hereof – specifically Purinethol, Tioguanine and Alkeran – were included in the list of medicines to be examined, but none of them was delisted after the evaluation carried out by AIFA's Technical Scientific Committee (CTS).<sup>33</sup>

---

<sup>27</sup> [Cf. doc. 5.]

<sup>28</sup> [Cf. art. 4, CIPE Resolution No. 3/2001 "[...] Should an average European price already be available, the administration can keep it into account."]

<sup>29</sup> [The system was defined by CIPE Resolution of 25 February 1994, amended by CIPE Resolution of 26 February 1998 and integrated with provisions of D.M. of 17 July 1998 and Law No. 448/1998 with reference to the calculation of the European Average Drug Prices (PME).]

<sup>30</sup> [To this regard, point 8.11 of the dossier annexed to the CIPE Resolution expressly provides for the company to indicate the investments carried out in research activities. Cf. note 26.]

<sup>31</sup> [Cf. doc. 5.]

<sup>32</sup> [Alkeran tablets 1969, Alkeran vials for injection 1999, Purinethol 1955, Tioguanine 1973, Leukeran 1982. Cf. doc. 124.]

<sup>33</sup> [Cf. doc. 112 and doc. 112, annex 5 and annex 6.]

53. Annexed to its brief, Aspen provided an exchange of e-mails between [Mr. F] - its representative in the negotiation with AIFA - and AIFA's offices, confirming the CTS's conclusions concerning the non-delisting (i.e., non-exclusion from the Code) of Aspen's drugs. In particular, in an e-mail from Mr. F to AIFA's Committee Secretariat dated 24 September 2013, Aspen's consultant stated to have found out, through a communication published by AIFA on its Internet website on 8 July 2013, that the CTS had planned an extraordinary meeting having as object the Review of the Drug Code and therefore asked "[...] to know whether, in the work carried out up to now, the following drugs have been taken into consideration [...]" (the list of Cosmos drugs followed, plus drug Myleran).

AIFA's answer dated 2 October 2013 stated "[...] with reference to the list of drugs you sent us, those object of the CTS's review were Purinethol (mercaptopurine), Myleran (busulfan), Leukeran (chlorambucil), for which the Committee deemed that there were no grounds for their delisting in the non-reimbursement Class." (editor's note, Class C).<sup>34</sup>

#### **III.4. DRUG DISTRIBUTION: OBLIGATIONS FOR THE VARIOUS SUBJECTS OF THE CHAIN AND TRACEABILITY SYSTEM**

54. The various subjects operating in the drug distribution chain are subject to supply and traceability obligations.

55. Article 105 and article 108 of D.Lgs. No. 219/2006 regulate the obligations for the various subjects operating in the drug distribution chain in Italy.<sup>35</sup> In particular, pursuant to article 105, paragraph 2, "Drug Marketing Authorisation holders and drug distributors of medicines introduced on the market must assure, within the limits of their responsibilities, appropriate and continuous drug supplies to pharmacies and authorised individuals so as to satisfy patients' needs."

Paragraph 3 of the same article specifies the maximum timeframe allowed for supplying drugs: "Drug supplies to pharmacies, also hospital pharmacies, or other subjects authorised to deliver drugs to the public [...] must take place with the utmost promptness and, however, within twelve working hours following the request."

Pursuant to paragraph 4 "Marketing Authorisation holders are obliged to supply drugs that cannot be found in the regional distribution network within forty-eight hours following the request of pharmacies, also hospital pharmacies, or drug sales points as provided for by article 5 of Decreto-Legge No. 223 of 4 July 2006, converted, with amendments, by law No. 248 of 4 August 2006."

56. D.Lgs. No. 17/2014 amended articles 105 and 108 of D.Lgs. No. 219/2006,<sup>36</sup> also in order to face the increasing amount of reports submitted by pharmacists and patients to the various Authorities (local bodies, AIFA, Ministry of Health) complaining drug shortage.

In particular, obligations were introduced for pharmacists and distributors to report any possible drug lack identified. In fact, paragraph 3-bis of article 105, D. Lgs. No. 219/2006 establishes: "Should the supply as mentioned under paragraph 3 not be carried out within the terms provided for thereby, the pharmacist, also through category associations, must report to the region or autonomous province or other cognizant authorities identified by the legislation of the region or autonomous provinces, the lack of the drug in the regional distribution network as well as at the wholesaler's to whom the request was submitted." Possible supply infringements are sanctioned pursuant to paragraph 3-quater of the same article, as well as with a suspension up to 30 days of the authorisation to distribute drugs.

#### **III.5. IMPORT AUTHORISATIONS AND DIFFERENCES WITH THE STANDARD SUPPLY REGIME**

##### **III.5.1 Commercialisation suspension and/or Marketing Authorisation withdrawal**

57. *In primis*, pursuant to article 34, paragraph 6, and article 38, paragraph 9, of D.Lgs. No. 219/2006 when withdrawing a drug from the market, the MA holder is obliged to communicate the termination of the commercialisation of said drug.

Specifically, article 34, paragraph 6, provides for the obligation of the MA holder to communicate to AIFA - with at least a two-month notice - the temporary or definitive termination of the commercialisation of the product, even when the reasons for said interruption are strictly commercial. The infringement of the mentioned obligation is not specifically sanctioned. Article 38, paragraph 9, regulates the holder's renunciation of the marketing authorisation.<sup>37</sup>

58. The administrative justice expressed its position on the interpretation of said regulations in favour of the entrepreneurial autonomy of the MA holder, deeming that AIFA has no "inhibitory interference" power toward companies that decide to interrupt the commercialisation of a drug and/or renounce the related MA. In fact, the TAR of Lazio, in ruling No. 8623/2012, stated that: "no national or community regulatory measure provides AIFA with an

---

<sup>34</sup> [Cf. doc 121, annex 1. It is hereby observed that Myleran is a specialty drug belonging to the anticancer drug package called Cosmos, which was object of the negotiation with AIFA, together with the drugs object of the investigation hereof. However, Myleran was considered obsolete by AIFA in all the therapeutic indications authorized and, therefore, its reclassification in Class C was authorised. ]

<sup>35</sup> [D.Lgs. No. 219/2006, "Implementation of Directive 2001/83/EC (and following amendments) concerning a community code referring to human drugs, as well as the Directive 2003/94/EC."]

<sup>36</sup> [In an answer provided by AIFA to a pharmacist reporting behaviours carried out by LFM and Aspen with reference to the distribution of Purinethol, the Regulator recalled the mentioned amended law observing that "it regulates exportation in such a way to impede the subtraction of critical medicines from availability on the national territory." Cf. doc. 21, page 23. ]

<sup>37</sup> [Cf. doc. 5.]

*inhibitory discretionary power [...] indeed, the possibility to revoke a company's renunciation does not fall within AIFA's discretionary power, as it can simply take notice of the act of renunciation expressed by the holder."*

In the same ruling, the TAR of Lazio reached similar conclusions with reference to the right to terminate the commercialisation of a drug, deeming that, on the basis of paragraphs 2 and 4 of article 105 of D.Lgs. No. 219/2006 regulating the obligations of the wholesale drug distribution, it is not possible to infer that the MA holder cannot suspend the commercialisation of a drug or renounce the related MA.<sup>38</sup>

59. In conclusion, on the basis of the regulatory framework in force and the interpretation of jurisprudence, the pharmaceutical company has both the right to suspend the marketing of a drug and the right to renounce the related MA.

### **III.5.2 Lack and shortage of drugs**

60. In the light of what stated by AIFA during the inquiry, it is necessary to make a distinction between a formal "shortage" and the mere lack of a drug within the distribution network. The shortage of a drug means "a drug that is not available or cannot be found on the market throughout the whole national territory because the MA holder cannot assure an appropriate and constant supply such to satisfy patients' needs."<sup>39</sup>

The shortage of a drug is ascribable to objective problems involving the MA holder, among which AIFA mentions problems related to production and distribution, impossibility to find the active ingredient, regulatory measures.<sup>40</sup>

In said cases, the MA holder must communicate to AIFA, with at least a two-month notice, the beginning of the state of shortage and the presumable conclusion.

On the contrary, a drug which is lacking in the distribution network cannot be defined a "shortage," and such situation is to be managed by identifying the cause of the phenomenon, often ascribable to parallel exportation. According to AIFA, the lack of a drug - "from a juridical viewpoint" - cannot be managed by authorising the import from abroad, because the MA holder regularly supplied the market with amounts capable of satisfying the internal demand.<sup>41</sup>

61. In case of shortage as described above, upon the request of single healthcare structures or of the MA holder, AIFA authorises the temporary importation from abroad of the drug in shortage.

This procedure is managed by AIFA's Products Quality and Counterfeiting Prevention Office, pursuant to D.M. 11 May 2001, "Procedures to be implemented in case of temporary shortage of specialty drugs in the national market." In such situation, AIFA highlights that:

- the amounts to be imported are defined on the basis of historic consumptions and orders coming from the single healthcare structure submitting the request;
- the MA Holder importing the drug in shortage from abroad is to transfer it to the SSN at the price in force for said drug in Italy, as expressly indicated in the authorisation to import;
- the price of the drug imported, if belonging to Class A or H, it is at the SSN's expense;
- patients, upon exhibiting the family doctor's and/or specialist's prescription, shall collect the drug exclusively at the hospital pharmacy that requested and received the drug imported by the MA holder;
- the product imported shall not be re-labelled, but must be provided with the patient information leaflet in Italian (MA holder's obligation);
- it is not possible to define with precision the timeframe within which the requesting healthcare structure must be supplied.

AIFA clarified that the import of drugs from abroad regulated by D.M. of 11 May 2001 represents an exceptional hypothesis.<sup>42</sup>

62. D.M. of 8 May 2003, "Therapeutic use of drugs subject to clinical experimentation," as amended by D.M. of 7 November 2008, regulates the modalities for importing drugs for experimental use, also defined "compassionate use," that is the individual and personal supply of drugs still subject to clinical experimentation to single patients or identified groups of patients affected by rare or severe pathologies, for whom there is no therapy authorised on the Italian territory and that have carried out - without success - all alternative therapies.

In these cases, the import authorisation request must be submitted by doctors who are obliged to indicate the names of the patients interested in following the therapy - which is why the programme is called: "Named patient based programme" - as well as the clinical reasons for the request.

D.M. of 8 May 2003 regulates specifically defined situations for the extraordinary supply of a drug, totally different from those that can arise following the MA holder's voluntary suspension of the commercialisation of a drug already authorised and widely used in Italy.<sup>43</sup>

---

<sup>38</sup> [Cf. doc. 5, annex 4. Ruling TAR Lazio No. 8623/2012.]

<sup>39</sup> [Cf. doc. 95.]

<sup>40</sup> [Cf. AIFA's website: <http://www.agenziafarmaco.gov.it/it/content/carenze-dei-medicinali>. Last accessed on 16 August 2016. ]

<sup>41</sup> [Cf. doc. 112.]

<sup>42</sup> [Cf. doc. 112.]

<sup>43</sup> [Cf. doc. 112.]

63. Lastly, according to the information provided by AIFA, besides the situations regulated by the Decrees mentioned above, should the MA holder suspend the commercialisation of a drug without giving prior communication to the Regulator, and should not submit an authorisation request to import from abroad, the only alternative possible to receive supplies lies in the autonomous drug import authorisation request submitted by the single healthcare administrations.<sup>44</sup>

In such case, the single healthcare structure that obtains AIFA's authorisation, purchases the drug directly from the MA holder, or from single intermediaries, but at the price defined by the seller, even bearing shipping costs.

## IV. OUTCOMES OF THE INVESTIGATION

### IV.1. RELEVANT MARKETS

64. For the purposes of the inquiry hereof, the relevant markets are those of the pharmaceutical products with the following active ingredients: melphalan, chlorambucil, tioguanine and mercaptopurine.

65. Generally speaking, in order to define relevant markets in the pharmaceutical sector, both the European Commission's resolutions<sup>45</sup> and the Authority's resolutions<sup>46</sup> refer to therapeutic classes, that is the chemical action and therapeutic purpose of a drug. These classes are identified in the Anatomical Therapeutic Chemical classification system (ATC), that divides drugs according to an alpha-numeric classification (based on five hierarchical levels), on the basis of standards provided by the World Health Organisation.

66. The third level of the mentioned classification, the ATC3, identifies a pharmacological therapeutic subgroup of drugs usually destined to the treatment of the same diseases, and which, in general, can be replaced but not with drugs belonging to other classes under the first and second levels. Therefore, the ATC3 is the level from which to start in order to identify products that cannot be replaced, which is the criterion that allows to define relevant markets.

67. Very often, however, it is necessary to carry out a specific replaceability analysis, mainly based on economic assessments, typical of antitrust analyses. This can lead to move away from the ATC3 level when "competitive restrictions" among companies are found at a different level within the ATC classification or when different criteria are used to group drugs. In fact, on the basis of what well-clarified by the European Commission, depending on circumstances, great relevance can also be given to prescription modalities or drug reimbursements, the general organisation of demand and supply.<sup>47</sup> In any case, it is clear that defining markets for antitrust purposes cannot disregard preliminary medical evaluations concerning the therapeutic replaceability of the products: it is essential, in fact, for the products being compared at economic level to be considered replaceable at therapeutic level by the competent scientific bodies and the scientific community.

In other words, therapeutic replaceability must be considered before and above economic replaceability, meaning that should products not be considered replaceable from a clinical-therapeutic viewpoint, the analysis of the economic replaceability of said products is useless.

In the AstraZeneca community case<sup>48</sup> and in the Merck and Glaxo national cases<sup>49</sup> the relevant market identified corresponded to level 4 of the ATC classification, while in several merger cases the Commission has circumscribed the relevant market to the single active ingredient.<sup>50</sup>

---

<sup>44</sup> [Cf. doc. 112.]

<sup>45</sup> [See, for example, cases IV/M072 Sanofi/Sterling Drug, Resolution of 10 June 1991; IV/M323 Procordia/Erbamont, Resolution of 20 April 1993; IV/M555 Glaxo/Wellcome, Resolution of 28 February 1995; IV/M587 Hoechst/Marion Merrell Dow, Resolution of 22 June 1995; IV/M737 Ciba Geigy/Sandoz, Resolution of 2 May 1996.]

<sup>46</sup> [Among the Authority's various measures see, for example: C/6341 Medeus Pharma/Varie società e ramo d'azienda, measure No. 12931 of 26 February 2004, in Boll. No. 9/2004; C/7010 Tyco Healthcare Italia/Altana Pharma, measure No. 14299 of 12 May 2005, in Boll. No. 19/2005; C/9073 Actavis Italy/Ramo d'azienda di Pfizer Italia, measure No. 17878 of 17 January 2008, in Boll. No. 2/2008.]

<sup>47</sup> ["At the third ATC level ("ATC3") pharmaceuticals are grouped in terms of their therapeutic indication, i.e. their intended use. This level is generally used as the starting point for investigating and defining relevant product markets in competition cases, in particular, for competition between innovator companies. However, it is appropriate to carry out analyses also at other ATC levels, or a mixture thereof, if circumstances show that sufficiently strong competitive constraints faced by the undertakings involved are situated at another level and there are indications that the ATC3 class does not lead to a correct market definition. The Commission has departed from the ATC3 class in cases where the market investigation indicated that another market definition was more appropriate, for example the ATC4 class or medicines based on the same active pharmaceutical ingredient (molecule level) [emphasis added] In the past, the Commission has considered that drugs available over-the-counter ("OTC") – i.e. without prescription – normally belong to a different product market than drugs available only on prescription. Medical indications, side effects, legal framework, distribution and marketing tend to differ between these drug categories, even if the active ingredients are sometimes identical. OTC pharmaceuticals can be advertised to the general public, whereas the advertising of prescription pharmaceuticals is restricted in most Member States. In most cases, consumers choose OTC pharmaceuticals themselves and purchases are not reimbursed. Prescription pharmaceuticals are prescribed by a doctor and part of the patient's purchase price is reimbursed by the public healthcare system. The commercialization of prescription pharmaceuticals is therefore targeted to prescribers and not patients." (Cf. Commission, Resolution of 17 July 2009, COMP/M.5476-Pfizer/Wyeth, §§ 15-17, [http://ec.europa.eu/competition/mergers/cases/decisions/m5476\\_20090717\\_20212\\_en.pdf](http://ec.europa.eu/competition/mergers/cases/decisions/m5476_20090717_20212_en.pdf)), last accessed on 31 August 2016.]

<sup>48</sup> [COMP/A. 37.507/F3 - AstraZeneca. With reference to said case, it is important to notice that both the EU Court (T-321/05, ruling of 1<sup>st</sup> July 2010, para. 154-155) and the Court of Justice of the European Union (C-457/10, ruling of 6 December 2012) confirmed the Commission's decision concerning the definition of the relevant market.]

<sup>49</sup> [Cf. cases: A363, Glaxo-Principi Attivi, 8 February 2006, Boll. No. 6/2006; A364, Merck-Principi Attivi, 21 March 2007, Boll. No.

68. In the case at hand, the drugs under consideration are anticancer products (antineoplastic agents, code ATC2, L01), used in the haematological field for the treatment of leukaemia, lymphoma, myeloma etc., and in specific phases of the treatment. Moreover, the mentioned drugs belong to two different ATC3 chemical-therapeutic subgroups: Leukeran and Alkeran are alkylating agents (ATC3, L01A), while Purinethol and Tioguanine belong to the antimetabolite class (ATC3, L01B). More precisely, Leukeran and Alkeran are "analogous to nitrogen mustards" (ATC4, L01AA), while Purinethol and Tioguanine are "analogous to purine" (ATC4, L01BB).

69. Each specialty drug considered has a different active ingredient (level ATC5). For each Cosmos drug under exam there are no other products on the market based on the same molecule: Aspen's drugs, in fact, have no direct substitutes since there are no generics of said drugs on the market, despite their patents expired decades ago.<sup>51</sup>

**Table n. 2: ATC classification of Aspen's drugs**

	Gruppo terapeutico principale (ATC di II livello)	sottogruppo terapeutico farmacologico (ATC di III livello)	sottogruppo clinico terapeutico farmc. (ATC di IV livello)	PRINCIPIO ATTIVO (ATC di V livello)
Alkeran	agenti antineoplastici (L01)	agenti alchilanti (L01A)	analoghi mostarda azotata (L01AA)	melifan (L01AA03)
Leukeran	agenti antineoplastici (L01)	agenti alchilanti (L01A)	analoghi mostarda azotata (L01AA)	docetubule (L01AA02)
Purinethol	agenti antineoplastici (L01)	antimetaboliti (L01B)	analoghi della purina (L01BB)	mercaptopurina (L01BB02)
Tioguanina	agenti antineoplastici (L01)	antimetaboliti (L01B)	analoghi della purina (L01BB)	tioguanina (L01BB03)

70. The two chemical-therapeutic subgroups mentioned, L01AA and L01BB, have different active ingredients, some of which are present on the market with drugs from other pharmaceutical companies.

However, on the basis of the information provided by AIFA and by GINEMA's independent haematologists (see *supra* § 11, note No. 5)<sup>52</sup> during the investigation, the drugs on the market with different active ingredients but destined to the treatment of several pathologies treated by Aspen's drugs cannot be considered fit for replacement from a therapeutic viewpoint: in fact, as it will be clarified hereafter, Aspen's drugs are used in specific populations of patients and in specific therapy phases for which no other drugs can be considered substitutes.

71. In particular, Purinethol and Tioguanine are mainly used in the treatment of acute lymphoblastic leukaemia (ALL) in children and the elderly respectively, and precisely in maintenance therapies at home. Leukeran is mainly used in the treatment of chronic lymphoid leukaemia (CLL) in elderly patients and in some forms of Non-Hodgkin lymphoma. Alkeran is mainly used in the therapy of multiple myeloma and it is a component in several cutting-edge protocols in combination with other anticancer drugs.<sup>53</sup>

72. According to the expert haematologists contacted by AIFA to evaluate the possibility of passing the examined drugs to Class C, the Cosmos drugs appear obsolete and surpassed by new treatments with reference to some of the therapeutic indications authorised. On the other hand though, with reference to the pathologies mentioned above (ALL, CLL, multiple myeloma and Non-Hodgkin lymphomas) the drugs under exam are still widely used and result to be irreplaceable.

73. To this regard, it is important to highlight that the therapeutic indications for which Cosmos drugs are still used correspond to pathologies that typically affect children and/or the elderly, as evident from the information provided in the "Tumour Guide" of the Italian Association for Cancer Research (AIRC).

In particular, AIRC states that CLL (the main disease treated with Leukeran) is "typical in the elderly," as "the average age of the diagnosis is around 65 years old" and "the percentage increases with the increase of age."<sup>54</sup> With reference to the Non-Hodgkin lymphoma (pathology treated with Leukeran) AIRC observes that "although in theory it can affect all ages, more than half of the Non-Hodgkin lymphomas involve people over 65 years of age."<sup>55</sup>

11/2007.]

<sup>50</sup> [Cf. M5295 Teva/Barr, 19 December 2008; M3544 Bayer Healthcare/Roche (OTC Business), 19 November 2004.]

<sup>51</sup> [Cf. doc. 94. ]

<sup>52</sup> [Cf. doc. 94. ]

<sup>53</sup> [Cf. doc. 94.]

<sup>54</sup> [Cf. <http://www.airc.it/cancro/tumori/leucemia/linfatica-cronica> (last accessed on 31 August 2016).]

<sup>55</sup> [In particular, chronic lymphatic leukaemia (the main disease treated with Leukeran) is "typical in the elderly," as "the average age of the diagnosis is around 65 years old" and "the percentage increases with the increase of age" (<http://www.airc.it/cancro/tumori/leucemia/linfatica-cronica>. Last accessed on 31 August 2016). Acute lymphoblastic leukaemia (the main disease treated with Purinethol) is the "most frequent childhood tumour," with "a peak of cases between 2 and 5 years old, which then decreases with the increase of age, to the point of being minimum after 29 years of age" (Cf. <http://www.airc.it/cancro/tumori/leucemia/linfoblastica-acuta>. Last accessed on 31 August 2016). The multiple myeloma (the main disease treated with Alkeran) represents "a tumour typical in the elderly" (Cf. <http://www.airc.it/tumori/mieloma-multiplo.asp>. Last accessed on 31 August 2016). With reference to the Non-Hodgkin lymphoma (pathology treated with Leukeran), AIRC observes that "although in theory it can affect all ages, more than half of the Non-Hodgkin lymphomas involve people over 65 years of age" (Cf. <http://www.airc.it/tumori/linfoma-non-hodgkin.asp>. Last accessed on 31 August 2016).]

As regards ALL (the main disease treated with Purinethol), AIRC states that it is the “*most frequent childhood tumour*” with “*a peak of cases between 2 and 5 years old, which then decreases with the increase of age, to the point of being minimum after 29 years of age.*”<sup>56</sup>

Finally, the multiple myeloma (the main disease treated with Alkeran) represents “*a typical tumour in the elderly.*”

74. Analogous information was provided also by GIMEMA’s haematologists,<sup>57</sup> whose considerations were crucial for reaching the conclusion that Cosmos drugs are electively used to treat diseases that affect weak patients, namely the elderly and children, particularly sensitive to the collateral effects of oncologic therapies.

GIMEMA’s experts emphasised the high tolerability of Aspen’s drugs. In fact, said drugs have been on the market for many years now and are historically used in the treatment of leukaemia: they have been greatly experimented,<sup>58</sup> they are characterised by an extremely low level of toxicity and by the absence of relevant collateral effects.

75. Moreover, with reference to the phase of the therapy in which they are used, oncologists state that the specialty drugs under exam are used in maintenance therapies at home, both in chronic patients and the so-called naïf patients.<sup>59</sup> This is due to their pharmaceutical formulation in tablets and their listing in the reimbursement Class A, which allows them to be distributed through territorial pharmacies. Said formulation does not require hospitalisation and infusion administration.

76. Lastly, when considering anticancer drugs, a key role is played by “*therapeutic continuity,*” which determines a strong rigidity of the demand also in the presence of therapeutic alternatives. With reference to chemotherapy drugs, patients’ resistance to change assumes particular relevance, because said drug category can cause collateral effects, even important.<sup>60</sup>

77. Therefore, from a demand viewpoint, the factors mentioned above constitute elements of extreme relevance, such to distinguish Cosmos drugs from the ATC4 substitutes on the market which are almost all for exclusive hospital use (including those in Class H): indeed, it is not at all irrelevant to be able to undergo a treatment without collateral effects and with simple tablets instead of a drip-fed infusion at the hospital.

78. These conclusions were confirmed also by the Party’s medical experts, who highlighted the characteristics of the mentioned Cosmos drugs, with particular reference to their tolerability - which distinguishes said products - and their irreplaceability in therapies for weaker patients. In particular, Aspen provided four opinions issued by two Italian haematologists ([*expert 1*]<sup>61</sup> and [*expert 2*]<sup>62</sup>) and two foreign experts (expert 3, [*Australian*]<sup>63</sup> and expert 4, [*British*]<sup>64</sup>), who evaluated the drugs under exam with reference to their irreplaceability, administration modalities and use for specific populations of patients (the elderly and children, that is weak patients). Their conclusions are provided hereafter.

79. All four experts agreed that Leukeran is the standard drug for treating CLL (“*a key drug,*” according to expert 4) and that, Leukeran “*represents a safe and effective treatment*” for elderly and weak patients (expert 2).<sup>65</sup> Said opinions highlight that CLL is a pathology typical in the elderly: expert 3 specified, in fact, that the first diagnosis of CLL is found in patients with an average age of 65-70 years old. Generally speaking, Leukeran is considered a useful treatment for elderly patients as they cannot tolerate highly aggressive treatments (expert 4).

According to expert 1, the envisaged introduction of Zydelig could reduce the use of Leukeran. In fact, the former drug, whose active ingredient idelalisib makes it fall within a different pharmacological therapeutic subgroup (L01X, “*Other antineoplastic agents*”), has been authorised in Italy for the treatment of CLL. However, the drug has been placed under additional monitoring, as indicated in the Summary of Product Characteristics (SPC).

In fact, on 23 March 2016, AIFA published an informative note on its website communicating to have taken important safety measures, in accordance with the European Medicines Agency (EMA), for the use of Zydelig in the treatment of

---

<sup>56</sup> [Cf. <http://www.airc.it/cancro/tumori/leucemia/linfoblastica-acute> (last accessed on 31 August 2016).]

<sup>57</sup> [Cf. doc. 94.]

<sup>58</sup> [With reference to how well the drugs are known and their consolidated use, GIMEMA’s representatives stated that “the drugs under exam are in no way subject to medical-scientific promotion [emphasis added], as it would be meaningless since these drugs have been on the market for more than 50 years and their use is widely consolidated. More in general, it is clear that, drugs used in the treatment of complex pathologies such as those under exam, are continuously subject to protocol experimentation. Moreover, it is frequent for haematologists to indicate to producers possible alternatives in the use of drugs. In such context, the role of pharmaceutical sales representatives is useless” [emphasis added] (doc. 94).]

<sup>59</sup> [A naïf patient is a patient who has just started a therapy for an unknown or not treated disease, and therefore has not already undergone a previous treatment with other drugs for the same pathology.]

<sup>60</sup> [Cf. doc. 94.]

<sup>61</sup> [Doc. 214, annex 14.]

<sup>62</sup> [Doc. 214, annex 15.]

<sup>63</sup> [Doc. 214, annex 16.]

<sup>64</sup> [Doc. 214, annex 18.]

<sup>65</sup> [Expert 2 added that “The rationale for using chlorambucil as the main chemotherapy element instead of the analogous of purine (such as, for example, fludarabine) is its milder toxicity in mono-therapy as highlighted in various (although not all) previous studies. Moreover, the superiority of the analogous of purine and other drugs compared to chlorambucil has not yet been demonstrated in the elderly and weak patients.”]

CLL and of the Non-Hodgkin lymphoma, since *“Intermediate results [...] have shown an increase in deaths associated to infections in the arm treated with idelalisib. [...]”*<sup>66</sup>

80. With reference to Alkeran, the four experts referred that the drug is mainly indicated in the treatment of multiple myeloma, usually diagnosed in patients ranging between 75 and 79 years of age (expert 3). Expert 4 stated that Alkeran is *“irreplaceable”* and that due to said irreplaceability a price increase would not lead to a substitution with other drugs. Expert 3 stated the lack of Alkeran substitutes in patients eligible for autologous stem cell transplant (*“no other drug has been shown to be as effective in this field, so there are no accepted substitutes”*).

As regards the tolerability of Alkeran, expert 1 stated, *“Despite alternative therapies allowed by MAs, often the only possibility in particularly weak patients is a treatment with melphalan (editor’s note: Alkeran)”* which remains irreplaceable in several essential protocols (*“irreplaceable for the use of bortezomib, thalidomide, drugs deemed indispensable for an optimal treatment of myeloma according to commonly accepted international standards”*). Also expert 2 qualified Alkeran for its *“low toxicity”* and *“administration by mouth.”*

81. The experts agreed in deeming Purinethol important for the treatment of ALL, and indispensable when it comes to children: expert 3 specified, in fact, that ALL not only is more frequent in children (from 2 to 4 years of age), but that it represents the most diffused childhood tumour. Also expert 4 stated the centrality of Purinethol in the treatment of children (*“core drug for the treatment of childhood Acute Lymphoblastic Leukemia [...]”*).

82. Further documentation highlights that also Aspen supports the uniqueness of the various drugs under exam in the treatment of several specific pathologies within the related pharmacological therapeutic subgroups (ATC3 level). In fact, Aspen emphasised this aspect in its reclassification requests submitted on 9 April 2013, at the beginning of the negotiation with AIFA. In said requests, Aspen stated for each product considered, *“[...] it is the only drug belonging to the category of alkylating antineoplastic agents [editor’s note, or] antimetabolites analogous to purine [editor’s note, ATC3 level] on the market in Italy for the treatment of [editor’s note, pathology].”*<sup>67</sup>

83. Furthermore, in a letter sent to AIFA in February 2012 with reference to the shortage of Aspen’s drugs in the distribution network, GSK (the previous MA holder of the drugs under exam) stated, *“[...] they are drugs without therapeutic substitutes, targeted to oncological patients affected by critical pathologies [...]”*<sup>68</sup>

84. In the light of the above, with reference to the therapeutic use, the differences with other drugs belonging to the ATC4 level can be summarised as follows:

- a) a different toxicity profile compared to other drugs on the market which are characterised by stronger collateral effects for patients, making them unusable for treatments in children and the elderly;
- b) the tablet formulation of Aspen’s drugs (with the exception of Alkeran, in injectable formulation) makes them more fit for an administration by mouth and, therefore, to be used in maintenance therapies at home, a phase of the treatment that can last for many years; their inclusion in Class A allows for their distribution through territorial pharmacies, upon presentation of a doctor’s prescription, while the other drugs with different active ingredients are mostly available in intravenous formulation and administered at the hospital (belonging to segment H); in fact, territorial pharmacies are the elective distribution channel of Cosmos drugs, as inferable from the data summarised in Table n. 3;<sup>69</sup>

**Table n. 3 – Percentage of Cosmos drugs purchased through the hospital channel and territorial pharmacies**

PRODOTTO	2013		2014	
	ospedaliera	territoriale	ospedaliera	territoriale
PURINETHOL	13%	87%	17%	83%
ALKERAN 50mg (polvere e solv.)	100%	0%	100%	0%
ALKERAN 25 cmp 2 mg	15%	85%	26%	74%
TIOGUANINA	16%	84%	23%	77%
LEUKERAN	10%	90%	17%	83%

Source: processing of AIFA’s data

- c) higher restrictive conditions set by AIFA for the therapeutic use of substitute drugs (for example, their use is allowed only in precise phases of the therapy and on the basis of a precise therapeutic plan, only when other drugs did not give a positive outcome due to a higher level of toxicity).<sup>70</sup>

<sup>66</sup> [Cf. <http://www.agenziafarmaco.gov.it/content/nota-informativa-importante-su-zydelig-idelalisib-23032016>. Last accessed on 17 August 2016.]

<sup>67</sup> [Cf. doc. 3, annex 1.]

<sup>68</sup> [Cf. doc. 14.10.14.]

<sup>69</sup> [Cf. doc. 124, annex 1, annex 2 and annex. 3.]

<sup>70</sup> [Cf., for example, therapeutic indications authorised for fludarabine and bendamustine based drugs.]

85. Lastly, AIFA's technical committee's opinion is deemed conclusive as it confirmed the appropriateness to maintain the drugs under exam at the SSN's expense, on the basis of their therapeutic irreplaceability highlighted by the oncologic experts contacted.<sup>71</sup>

86. In conclusion, the absence of therapeutic replaceability between the specialty drugs considered and other ATC4 level drugs on the market allows to define the relevant market with reference to the single active ingredient (ATC5). Therefore, from a product analysis viewpoint, on the basis of what examined, it was possible to identify the following relevant markets, in which only Aspen's drugs are present, as indicated in parenthesis:

- melphalan-based drug market (Alkeran in tablets and Alkeran in vials for injection);
- chlorambucil-based market (Leukeran);
- mercaptopurine-based market (Purinethol);
- tioguanine-based market (Tioguanine).

87. The markets for the production and commercialisation of drugs, from a geographical viewpoint, are traditionally considered national, both by the European Commission and the Authority. This due to the differences among healthcare policies of the single Countries (i.e. price regulations, reimbursement modalities, drug classification, distribution channels) and of the various access regimes (i.e. patent regimes and marketing authorisations).

For these reasons, the extension of each market identified above is limited to the national territory.

88. The size of the relevant markets, assessed on the basis of the new prices approved by AIFA, is equal to about [5-10] million Euros a year, according to the specific turnover communicated by Aspen and referring to the last fiscal year closed (July 2015-June 2016).<sup>72</sup> To this regard, it is important to observe that hematologic diseases represent a subgroup of tumours whose size (in terms of numbers of patients) is limited, if compared to that of the so-called "solid tumours."

Aspen is the only MA holder for the commercialisation in Italy of drugs with the active ingredients under exam. Therefore, the undertaking is monopolist in the relevant markets identified.

#### **IV.2. ASPEN'S STRATEGY IN THE NEGOTIATION WITH AIFA**

89. The investigation allowed to distinguish two main phases in the negotiation between Aspen and AIFA:

i) in the first negotiation phase, APTL submitted a specific request to AIFA - received on 17 April 2013 - concerning the reclassification in Class C of the drugs object of the inquiry;<sup>73</sup>

ii) in the second negotiation phase, the CTS first declared - on 10-11 September 2013 - the inadmissibility of APTL's request, and then on 17 March 2014 AIFA decided to redefine prices.

90. The various phases of the negotiation were carried out for the Aspen group by different people. In the first phase of the negotiation, APTL appointed Mr. F from the consultancy studio having the same name; in the second phase, upon Mr. F's request, the company appointed Mr. E to negotiate with AIFA with reference to the price increase request for the drugs under exam.<sup>74</sup>

##### **IV.2.1 Class C reclassification request**

91. On 13 April 2013 Aspen submitted distinct requests - which AIFA received on 17 April 2013 - asking for the variation of the reimbursement regime of the specialty drugs object of the investigation and of drug Myleran.<sup>75</sup> Specifically, the request was to pass from class A-RNR, subject to SSN's reimbursement with non-repeatable prescription (ricetta non ripetibile - RNR), to class C, at patients' total expense; with reference to Alkeran in injectable formulation, the request was to pass from class H to class C.<sup>76</sup>

As highlighted also by AIFA, the reclassification requests were submitted "[...] in order to obtain the alignment of the sales prices of the specialty drugs with the prices applied in the other EU countries which, according to what stated by the requesting company, are higher."<sup>77</sup>

As highlighted in the section concerning relevant markets (cf. *supra*, sect. IV.1), each reclassification request of the drugs considered emphasised the uniqueness of the products for the treatment of severe oncologic pathologies.

92. During the hearing, AIFA specified that the fact that the negotiation was opened with the request to pass Aspen's drugs into Class C "was a totally exceptional circumstance: in fact, it is the first case ever occurred for anticancer drugs, given their life-saving nature and irreplaceability, as certified by expert haematologists [...]"

---

<sup>71</sup> [Cf. doc. 3, annex 2, 3, 4, 5.]

<sup>72</sup> [Doc. 225.]

<sup>73</sup> [On the same date, a similar request was submitted for the specialty drug Myleran.]

<sup>74</sup> [Mr. E, former employee of GSK, is currently General Manager of AI, and has been since the company's establishment. Cf. doc. 95 annex 1 and 1-bis, doc. 97.]

<sup>75</sup> [Cf. doc 3, annex 2: "Reception date of the request: 17 April 2013."]

<sup>76</sup> [The request refers to "Class C," and not to the so-called non-negotiated Class C introduced by Decreto Balduzzi and described under § 33]

<sup>77</sup> [Cf. doc. 3.]

AIFA added that the request to pass to Class C at the citizens'-patients' expense "undoubtedly represented an aggressive behaviour in the company's negotiation with AIFA."<sup>78</sup>

93. Upon receiving the mentioned requests, AIFA's CTS asked for the opinion of an external group of expert oncologists concerning the admissibility of Aspen's reclassification requests.<sup>79</sup> On 18 July 2013, the experts expressed a negative opinion concerning the possibility for Aspen's drugs to be passed into Class C on the basis of the following consideration: "Some indications of the specialty drugs under exam are obsolete and therefore not used, but others are considered indispensable."<sup>80</sup> The experts reached this conclusion for all of the specialty drugs object of the proceedings. With reference to Myleran, instead, the Committee of oncologists stated that said product "[...] is not deemed indispensable in none of the indications."

94. The CTS held a first meeting on 10 and 11 September 2013. Aspen's request is summarised in the minutes of said meeting as follows: "Company's note: The requesting company needs to urgently obtain a significant increase in sales prices in order to align the prices in force with those of the main EU Countries. [...] Office's note: The company is requesting the reclassification from Class A-RNR to Class C so as to align the sales prices with the EU prices (considerably higher according to what stated by the company)."<sup>81</sup>

The mentioned minutes contain the CTS's decision based on the mentioned committee's opinion: "Having considered the Class C reclassification request, the CTS asked the company to formulate a price proposal that allows to keep the drug in the regime that provides for the SSN's reimbursement. Letter to the company. Procedure suspended."

95. With reference to the matter, AIFA clarified that the CTS, "[...] after in-depth evaluations with the group of expert oncologists, deemed that the mentioned drugs were characterised by several "essential" therapeutic indications; therefore, it appointed AIFA's Pricing and Reimbursement Committee (CPR) "to re-evaluate with the company a fair increase" of prices so as to **remain in Class A or pass to Class H** [...] The only specialty drug that the CTS deemed to be "obsolete" was MYLERAN, for which the reclassification request into Class C was accepted."<sup>82</sup>

#### **IV.2.2 Threat to suspend the supply and reiterated request to pass into Class C**

96. AIFA thus asked the company to formulate a price proposal, which arrived through Aspen's letter dated 14 October 2013. In the letter, provided hereafter, the company reiterated the need to obtain a significant increase of prices so as to align them to the average prices in force in the EU. In fact, Aspen insisted on the need of a quick decision by AIFA setting a deadline beyond which, if the price proposal had not been accepted or, in alternative, if the request to pass the drugs under exam to Class C had not been accepted, the company would have suspended the direct commercialisation in Italy and would have supplied Italian patients through quantitatives arriving from other EU countries at the price in force therein:

*"On the basis of what indicated in the drug reclassification requests filed on 13 APRIL 2013 for ALKERAN (injectable and tablets), LEUKERAN, MYLERAN, PURINETHOL, TIOGUANINE ASPEN, it is a priority for Aspen to quickly reach a significant increase in sales prices, regardless of the possibility to remain in the current reimbursement class, although hoping to remain.*

*Taking into consideration how remarkably dated is the registration of the products mentioned and the parameters established by CIPE Resolution No.3 of 2001, inferable in their whole by the regulations in force, it seemed demanding to submit a price increase request and ask to maintain the reimbursement classification at the same time [emphasis added].*

*Moreover, when asking to access the procedure related to the Review of the Drug Code, we were informed by the Office for the Joint Coordination of Secretariats (Ufficio Coordinamento Segreterie Organismi Collegiali) that AIFA had evaluated the possible delisting of three of the drugs object of the reclassification requests (LEUKERAN, MYLERAN, PURINETHOL).*

*Nonetheless, although the negotiation lasted more than what hoped [emphasis added], we appreciate the Technical Scientific Committee's decision not to exclude a priori the fact of maintaining the reimbursement of the products, even granting a relevant price increase [emphasis added]. In fact, we hope that the decision kept into account the irrelevant size of prices currently in force, especially if proportioned to the costs necessary to carry out an activity aimed at providing updated medical information on the products. In the specific case, said activity envisages the use of the examined drugs in combination with cutting edge drugs, as well as pharmacovigilance according to modalities recently entered into force in the EU countries that are much more onerous; and lastly, from the productive viewpoint, the maintenance of GMP standards (the so-called "special requirements") with reference to the toxicity of the products. Finally, it is important to consider the need to align prices in the various EU Countries so as to guarantee price sustainability and supply satisfaction in the respective markets.*

---

<sup>78</sup> [Doc. 84.]

<sup>79</sup> [Doc. 84.]

<sup>80</sup> [Cf. doc. 3, annex 5, "Oncologic transversal activity: Oncologic consultation minutes."]

<sup>81</sup> [Cf. doc. 3, annex 2.]

<sup>82</sup> [Cf. doc. 3, pages 1 and 2.]

Therefore, in view of a possible negotiation, we annex hereto the required documentation providing prices (data on prices with the requested price) and volumes of the main EU markets, including those where price renegotiation is still ongoing, among which, looking at the markets of reference, Spain, Belgium and the Netherlands; said documentation also provides a presentation of the multinational group, with its investment plan in the EU area; in particular [...]

All that being said, going back to the company's priority mentioned above, we highlight the precise value within which the abovementioned prices are submitted through the annexed formats called "drug data":

should this office be able to proceed and quickly conclude (November 2013) this reimbursement negotiation, ASPEN is fully at disposal to meet at AIFA's premises or however to evaluate a possible answer/counterproposal.

Whereas, should the prices be too far from expectations or however should it be impossible to define within the time frame indicated a definitive assessment concerning reimbursement, the prices provided shall be considered effective for the drug price publication according to a new classification in Class "C", while waiting for a possible reopening of a negotiation upon AIFA's request, in case, even after analysing the market trend following the reclassification.

Should AIFA be able to make its decision within the indicated deadline, ASPEN undertakes to apply the price increase (in class "C" or with the new prices in class "A") starting from February 2014.

Whereas, should no decision be made within the deadline indicated concerning the new prices negotiated or in alternative the new classification and drug price in Class C, we shall promptly proceed pursuant to law to communicate the suspension of the commercialisation of the products in Italy, starting from January 2014. In said case, drugs shall be available for Italian patients through the markets of the other EU countries at the prices in force therein."<sup>83</sup>

97. In this phase of the negotiation, upon AIFA's request, Aspen produced data concerning prices, turnovers and sales volumes realised in various EU countries through the selling of the specialty drugs considered, on the basis of which the Pricing and Reimbursement Committee (CPR) determined the "actual" sales prices for each country.

The data provided by the undertaking and indicated in the minutes filed by AIFA, show that between 2012 and 2013 prices were increased in various European countries. Mr. A., APTL's General Manager, explained during the inspections that the Aspen group had started a review process for price increases of its oncologic products in all of Europe. The strategy was defined by the South-African holding and implemented with different modalities at local level.<sup>84</sup> This seems confirmed by the involvement of APL's representatives in many e-mail exchanges, collected during inspections, referring to the negotiation with AIFA. In particular, there are important messages from Mr. B, in quality of Group Commercial Executive of the South-African holding.

98. In an e-mail dated 17 October 2013, collected at AI's premises in Verona, Mr. F commented the minutes of 10 September 2013 in which AIFA's CTS appointed the Pricing Office to ask the undertaking to formulate a price proposal, following the evaluation of the therapeutic irreplaceability of said drugs and the need to keep them in the reimbursement class: "...the minute [editor's note, the CTS's minutes] is very interesting and let know the validness of our strategy..." [emphasis added].<sup>85</sup> Aspen qualified the request to pass into Class C as a strategic choice, as it induced the CTS to pronounce on the irreplaceability of the drugs.

The document filed contains a comment written by hand that summarises the content: "AIFA's answer concerning Class "C" is important – a price is requested."

99. An e-mail sent on 25 October 2013 from Mr. F to Mr. B and other Aspen representatives, with object "Re: Contact with Mr. G," mentions the telephone conversation between Mr. F and Mr. G, head of AIFA's Pricing Office, in view of the CTS's following meeting in which the price increase proposed by Aspen was going to be discussed, initially planned for the end of October 2013 and then held on 6-8 November 2013. The text highlights Mr. F's awareness concerning the lack of valid justifications for obtaining such significant price increases and Mr. G's critical position.

The e-mail states as follows: "[...Mr. G, editor's note] has been able to give me fifteen minutes by phone this afternoon [...] I've underlined that Aspen now is at disposal for proceeding with a negotiation but under condition of respecting the deadline indicated in the replay.

I let him understand that, the worst thing that the Company would see is silence or signs of delaying strategy by AIFA. By his side [Mr. G, editor's note] wanted me to refer to ASPEN that, if six months [that is, the 180 days provided for by law for AIFA's inquiry into the reclassification requests, editor's note] is considered a long/unacceptable time to decide a price increase, also evaluating and accepting a price increase of a medicinal only because of the change of marketing authorization holder is very difficult for a Regulatory Agency [...] [emphasis added].

I've made him see that the Company has found a very long time six month for only receiving replay that a negotiation for reimbursement is necessary and he has replaid that the Company should consider that for AIFA is not easy accepting that medicinal products go to C class with a significative prices increase [emphasis added], in the end, by the point of view of national pharmaceutical service (as we didn't mention any strong base other than the prices in UE, for asking an increase of prices) [emphasis added] just because of the change of the marketing authorization holder. [...]

---

<sup>83</sup> [Cf. doc. 5, annex A.]

<sup>84</sup> [Cf. doc. 44 and doc. 97.]

<sup>85</sup> [Cf. doc. 12.27.]

[Mr. G, editor's note] *has let me understand a detail on the dynamic of AIFA in evaluation regarding price: apparently, though I thought it was relevant prevalently for the decision for reimbursement or not, instead has importance also for according its price level (and also in a product of old registration!), the precise detection of efficacy level ascribed, according to current scientific knowledge, to the medicinal product for each single indication (in short, the ascribed strong efficacy in an indication for a severe pathology, put – in general – AIFA in condition to provide more resources for this product). [...] more resources can be destined for the product considering how the same actually helps patient for a specific severe indication). [...] [emphasis added].*<sup>86</sup>

100. Basically, the last part of the summarised conversation between Aspen's consultant and the head of AIFA's Pricing Office highlights that, due to the difficulty in allowing both the passing into Class C and a high price increase concomitantly, AIFA was willing to grant a significant price increase, if the CTS excluded the possibility to pass a drug into Class C owing to its relevance in the treatment of severe pathologies.

101. The minutes of the CTS's meetings held on 6 and 8 November 2013 refer to the reception of Aspen's price proposal and indicate the launching of the CPR's investigation on 19 November 2013, which concluded with a meeting organised by the CPR and held on 16 December 2013, with Aspen's participation.<sup>87</sup>

102. The content of the letter of 14 October 2013 is mentioned in the CTS's minutes: "*The company makes known with letter dated 14 October 2013 to be interested in maintaining the specialty drugs object of the reclassification request in the reimbursement regime, and therefore submitted price proposals hereafter.*" It is important to observe that these first price proposals of Aspen's were extremely high, of the same relevance of those established by the outcomes of the negotiation with AIFA.

103. In the period of the CPR's investigation (19 November 2013 – 16 December 2013), the documents filed show a series of considerations carried out internally by the representatives of the Aspen group, which are important for identifying Aspen's strategy. Two e-mails in particular are relevant.

The first, dated 5 December 2013, sent from Mr. B to Mr. E and in copy to [Mr. H] and Mr. F – with object: "*Italy – CONFIDENTIAL*" – summarises the negotiation strategy that Aspen intended to adopt in its following meeting with AIFA, highlighting the intention to reiterate the request to pass to Class C and threat the suspension of the supply on the Italian market, if AIFA did not accept the price proposals formulated:

"Hi [Mr. E, editor's note],

*high level summary of call in preparation of your meeting with [editor's note, AIFA]*

*Europe:*

- *We have implemented the pricing across Europe – per below*
- *Key markets remaining are – Spain – Italy – (Portugal 3 sku's pending)*

*Italy history:*

- *Application made in April (Davide can confirm)*
- *We applied for C-class delisting*
- *Have received approval on Myleran but CTS need the other products so the C class was rejected – as such Price Office require a negotiation*
- *We have told them we can enter negotiation but we only have until January to supply the product [...]*
- *Legally we cannot be stopped supplying the products but we would obviously do this in a responsible way for patients and would like to manage our relationship with AIFA*

*MOH Meeting objectives:*

- *Get agreement on a price versus Germany - our floor is French prices (approx. 70% of DE prices)*
- *If this can't be agreed then push hard to get C class on all products so we have free pricing and we will then put strategy in place to optimize regional reimbursement*
- *If this can't be agreed we will initiate supply termination in January until item can be resolved - Italy will need to procure in EU via parallel trade at the new prices.*<sup>88</sup>

104. Analogously, a second e-mail sent on 10 December 2013 from Mr. B to Mr. E and Mr. F, having as object "*Italian MOH price meeting – 17 Dec 10:45 a.m.*" reasserts Aspen's aims and negotiation strategy:

"*To ensure clarity for the upcoming meeting the objective would be to get agreement on the target prices per below in red – the floor price (lowest) for negotiation and in meeting agreement is the French price see below (i.e. btw 80-100% of target)*

*Should AIFA not agree to pricing in this range we should then obtain approval to delist the remainder of the products from reimbursement per our initial request to avoid a January exit from the market[.]*

*Should this not be achievable we would initiate the January exit and suspend supply if/until the pricing can be resolved – we would work responsibly with AIFA on the exit to ensure proper communication in market...*<sup>89</sup>

---

<sup>86</sup> [Cf. doc. 12.25.]

<sup>87</sup> [Cf. doc 3, annex 5, p. 10.]

<sup>88</sup> [Cf. doc. 12.7.]

<sup>89</sup> [Cf. doc. 12.8.]

105. The meeting at AIFA's premises between the undertaking and the CPR was held on 16 December 2013. The minutes filed by AIFA report the debate between the parties of the negotiation concerning the price increase proposals of Aspen's drugs. Relevance is given to the CPR's position regarding the unacceptability of the prices proposed for the SSN, as well as Aspen's Class C reclassification request, to which the CPR answered highlighting once again the essentiality of the drugs under exam asking the Party to formulate a new price proposal. As written in the minutes:

*"Entry of the company at 10:40 a.m.*

*Company*

*Update concerning drug prices in the EU: In Spain price renegotiation is ongoing;*

*In the Netherlands a price review has been requested*

*CPR*

*The increases proposed by the company are not bearable by the SSN.*

*A price aligned to the lowest average price applied in the three EU countries is considered acceptable [emphasis added]. A price reduction/discount for the SSN was requested with reference to the supply price, taking into consideration the actual ex factory price applied in the EU countries (on the basis of the sales data transmitted by the company)*

*The Company asked to interrupt the negotiation in order to inform the Parent Company of the Committees' new proposal (at 11:14 a.m.)*

*Entry of the company at 11:50 a.m.*

*Company*

*The Class C delisting proposal was reiterated [emphasis added], with the availability to renegotiate drug prices in February, awaiting the consolidation of the sales data in the EU countries.*

*CPR*

*Taking into consideration the CTS's opinion concerning the essentiality of said drugs, the company's request resulted not acceptable [emphasis added].*

*It is proposed to exclude Austria, due to the different reimbursement/distribution mechanisms, and therefore to consider the other EU countries to identify the average price.*

*The CPR's decision:*

*The Committee asked the company to formulate a new price/SSN discount proposal, [emphasis added] in consideration of the indications expressed by the CPR to the company.*

*Therefore, a formal proposal is awaited. The procedure is suspended."<sup>90</sup>*

106. In an exchange of e-mails between Mr. F and Mr. B dated 19-20 December 2013, Aspen's consultant mentioned AIFA's position concerning the company's price requests. Mr. F explained that AIFA insisted to maintain the drugs under exam in Class A. However, given the significant price increase requested and the non use of the usual criteria followed to approve price increase reviews, AIFA still had to anchor its decision to an international comparison based on effective prices, net of discounts applied to the healthcare systems.<sup>91</sup> The e-mail text is as follows:

*"[...] AIFA strongly wants to keep the products in "A" but, because of the significant increase requested by ASPEN and the lack of criteria ordinarily admitted for approving a price increase [emphasis added], as well strongly needs to anchor this decision to a precise reference to effective prices charged by Aspen (including relevant discounts) to national health care systems in the EU Countries taken as reference countries.*

*Examining the documents regarding prices, sales and values, CPR has noticed the relevant difference between the amount expected considering the simple division of the value for the products units sold, and the amounts indicated by ASPEN as the new prices in force.*

*CPR, has deduced that effective net prices charged by ASPEN in EU, are far from the ones indicated as official new prices.*

*CPR would like to fix the new increasing prices in Italy as an average of the effective (new) prices in EU [emphasis added], through receiving by ASPEN the following data:*

*official documents that show the date of entering into force of new prices in each reference Country (possibly, France, Germany, UK, Austria, Belgium, Denmark, Greece, Ireland, Portugal, Netherland); [...].<sup>92</sup>*

#### **IV.2.3 Second price proposal and conclusion of the negotiation**

107. According to AIFA's minutes, Aspen submitted its second price proposal on 16 January 2014, through AIFA's procedure online.<sup>93</sup>

The CPR met again on 29 January 2014 to discuss Aspen's second price proposal. The prices object of Aspen's new proposal were substantially similar to the first prices proposed.

---

<sup>90</sup> [Cf. doc. 3, annex 5, p. 11.]

<sup>91</sup> [Cf. doc. 12.35 B.26.]

<sup>92</sup> [Cf. doc. 12.35 B.26.]

<sup>93</sup> [Cf. doc. 3 annex 5, pages 11-12.]

Moreover, AIFA's minutes indicate that Aspen did not comply with what required by the CPR in the previous meeting, not establishing the average European price on which to anchor the new Italian price on the basis of the effective prices applied by Aspen in the various EU countries, net of discounts. In fact, it is possible to read in the minutes provided by AIFA:

"29 January 2014 –CPR MEETING

16 January 2014 – the company annexes its price proposal (ALC and online Negotiation System).

[...] In the new proposal, in order to identify the average price applied, unlike what clarified with the company in the above mentioned meeting, the effective prices were not considered [emphasis added] (Turnover of the specialty drug considered/Sales volumes), rather the nominal price net of possible discounts was considered [emphasis added](as inferable in the integration submitted by the company in the ALC and in the online Negotiation System).

108. Despite the substantial similarity between the second and first price proposals (deemed unbearable by AIFA for the SSN), on 31 January 2014, only two days after the meeting between Aspen and CPR, the Parties signed a negotiated agreement on the new prices of Aspen's drugs, as highlighted by the documents filed.<sup>94</sup>

109. With decision of 17 March 2014, AIFA approved the new *ex factory* prices and the prices to the public of the drugs under exam, as shown in Table 1, and reconfirmed for all of said drugs the reimbursement at the State's expense (class A or class H). The prices approved by AIFA correspond to an increase ranging between 300% and 1,500% of the initial prices.

110. After the approval of the new prices, on 31 January 2014, Mr. F wrote an e-mail to Mr. B and Mr. A with object "Target prices achieved in Italy!", informing them in an enthusiastic tone of the excellent result achieved: "I [...] am happy to communicate you that this morning we've signed new reimbursement and price agreement successfully: price increases are basically on line with European target prices (Leukeran, a bit higher!). I wouldn't expected to conclude the negotiation so favorably, but I remember when you've told me in Rome that everywhere at the beginning it seems it was kind of "mission impossible" and then the prices increase where always authorized...Let's celebrate!" [emphasis added].<sup>95</sup>

#### **IV.2.4 Stock allocation system: lack of Cosmos drugs as negotiation lever**

111. The documentation collected during inspections highlights that the Aspen group manages an allocation system of oncologic products among the various geographical markets in which it operates.<sup>96</sup> This system, called "Oncology Allocation Programme," allows to plan the product quotas that from the stocking site of Bad Oldesloe in Germany are to be distributed to the various national markets. With reference to the allocation system of the quantities described, during the hearing Aspen stated that "[...] the tool allows to have an overall view of the supplies of oncologic products in Europe, in order to programme production. It is a mechanism that, from Aspen's viewpoint, is aimed at maintaining a stable and continuous supply, satisfying the local demand of the various countries. The data on the local demand are provided by the marketing team and used for forecasts on the basis of which a supply programme is organised: the attempt is for such plan to be based on [20-25] months, but in practice the timeframe of reference is [1-5/5-10] months, also due to the need of flexibility even in the light of production problems that have occurred and that can occur every once and a while causing the inefficiency of the supply chain."<sup>97</sup>

112. With specific reference to Italy, in an exchange of e-mails within the group dated 17 January 2014, [Mr. I] (Europe Supply Chain) stated: "We ship weekly quotas from Aspen Bad Oldesloe to LFM based on Aspen's enforced sales quotas [emphasis added], to ensure there is stock in the market at all times. LFM sold above quota when they first took over distribution from GSK but since August 2013, sales have been pretty much aligned to the quota. In the past 3 months, they are actually selling below quota for most of the products. If there are stock issues, then the stock must be leaving Italy through parallel exports or the sales quota being enforced does not truly reflect the real market demand." [emphasis added]<sup>98</sup>

113. In an exchange of e-mails dated December 2013 between [Ms. A], Head of Export and Contract Manufacturing Department of LFM, Aspen's distributor for Italy, and Aspen's top management, [Mr. B] mentioned the dissatisfaction expressed by the wholesaler [Mr. L] concerning the quota of Cosmos drugs imposed on distributors, a policy adopted by Aspen through LFM: Mr. L complained the reception of 3 to 5 reports every week from territorial pharmacies concerning the non-supply of Cosmos drugs. Ms. A referred to Aspen that Mr. L threatened to suspend the distribution relationship with LFM, for the company's entire list, if not granted the supply of 100 boxes a month of Alkeran, necessary to satisfy the requests of the pharmacies supplied by the wholesaler (Mr. L stated to have received only 4 boxes of Alkeran in the previous two months).<sup>99</sup>

<sup>94</sup> [Cf. negotiation agreements between AIFA and Aspen, documents 12.19, 12.20, 12.21, 12.22, 12.23.]

<sup>95</sup> [Cf. doc. 20.18.]

<sup>96</sup> [Cf. documents 12.35 B.2, 12.35 B.21.]

<sup>97</sup> [Cf. doc. 97.]

<sup>98</sup> [Cf. doc. 12.35 B.2.]

<sup>99</sup> [Cf. doc. 12.35 B.19. In fact, Ms. A referred to Mr. B: "Our wholesaler [...] points out that his customers complain about the fact that they cannot be supplied by him with Purinethol and the other Cosmos products. The complaints are in the range of 3 to 5 a week. [Mr.

114. Basically, the allocation system of Aspen's products seems aimed at containing the commerce of parallel market flows caused by the differences in drug prices among Countries. However, the quotas established by Aspen for the Italian market are not always capable of satisfying the internal demand, as inferable from the documentation mentioned in the following paragraphs.

115. The shortage of Aspen's oncologic products in the Italian pharmaceutical distribution network during the first months of 2014 - period prior to the redetermination of their prices - was object of various reports submitted by patients and pharmacies, collected in the mentioned investigation carried out by Altroconsumo (see *supra*, § 4). Said documents indicate that Aspen was aware of the problem, and that it intervened to modify the quotas targeted to the Italian market following the reports of shortage, so much so that AIFA then summoned the representatives of the group to obtain clarifications concerning the issue (cf. *infra*, § 120).<sup>100</sup>

116. During the inquiry, the Directorate received a report from a pharmacist in Trieste, also president of the Association Genitori Malati Emopatici Neoplastici, that produced elements on Aspen's drug lack management in the Italian distribution network.

The reporting pharmacist provided a copy of his personal correspondence with Aspen's Italian distributor (LFM) and with AIFA confirming:

- first of all, that the drug Purinethol was lacking on the Italian market in the negotiation period (from December 2013 up to the determination of the new price in March 2014);
- that following the product request submitted by the reporting pharmacist pursuant to article 105 of D.Lgs. 219/2006,<sup>101</sup> LFM required specific documentation proving oncologic patients' actual need of the product requested (10 boxes).<sup>102</sup>

117. Having been informed about the problem at the beginning of December 2013, on 16 December 2013 AIFA immediately pronounced on LFM's request of a copy of prescriptions and orders for Purinethol defining the request "arbitrary and illegitimate", "[...] not finding foundation in any provision of law related to the matter. In fact, the MA holder has no competence or right to verify the legitimacy and/or appropriateness of the request [...]".<sup>103</sup>

118. In an internal e-mail sent from Mr. E to Mr. I on 17 January 2014 - therefore, in the period between Aspen's new price proposals (16 December) and the second negotiation with the CPR (29 January) - Mr. E's concern emerges with reference to the excessive imposition of quotas carried out by Aspen in Italy, with allocation quotas significantly below the average sales of the previous eight months. Said e-mail also highlights Mr. E's concern with reference to the risk that said information could influence negatively the negotiation with AIFA: "[...] I have to underline that the allocation quotas for Alkeran Vials and Tablets is significantly below the average sales of the last 8 months. I think that this could have an impact on products availability and performance and should AIFA get to know this info, they could be able to use it to their advantage [emphasis added]."<sup>104</sup>

119. Basically, through its supply chain management, Aspen was able to determine the quantitative of Cosmos drugs destined to the various Countries, also on the basis of price differentials. Moreover, the quantities defined for the Italian market through the oncology allocation programme determined supplies below those needed for the Italian market, as complained by the wholesaler Mr. L, as well as the reporting pharmacist from Trieste and as stated by Mr. E in the mentioned correspondence (cf. *supra*, § 113).

120. On 22 January 2014, AIFA summoned Aspen's and LFM's representatives to discuss the reiterated reports received concerning the lack of Cosmos products. In said meeting, Aspen's representatives stated the availability to increase the quantities of product to destine to the Italian market, upon verification with the production site. During the hearing, Aspen confirmed that, after the meeting with AIFA, it increased the quantities destined to the Italian market by 10%.<sup>105</sup>

121. In this context, an e-mail dated 4 April 2014 from Mr. E (Aspen) to several APIL employees (among whom the manager of the supply chain) is of particular importance, as written after the entering into force of the new prices in Italy. In fact, said e-mail highlights the intention to proceed with an increase of the quantities destined to the Italian market after the approval of the new prices: "I am very happy to announce the publication in the Official Journal of the new prices for all the Cosmos products [...] before scratching out the allocation system for this product, I would like to evaluate sales trend at least for one month [...] Please be prepared for a possible shipment quotas increase. [emphasis added]."<sup>106</sup>

---

*L] also points out that - although unhappily but according to our guideline - he has always justified the lack of product as the direct and only consequence of our policy".]*

<sup>100</sup> [Cf. documents 12.35 B.19, 12.35 B.8.]

<sup>101</sup> [Art. 105 Lgs.D. 219/2006: "the MA holder is obliged to provide drugs that cannot be found in the regional distribution network within forty-eight hours, from pharmacies' request, also hospital pharmacies."]

<sup>102</sup> [Cf. doc. 21.]

<sup>103</sup> [Cf. doc. 21.]

<sup>104</sup> [Cf. doc. 12.35 B.34.]

<sup>105</sup> [Cf. doc. 6.]

<sup>106</sup> [Cf. doc. 12.35 B.33.]

122. In another document filed, Aspen indicated more clearly that there was no longer the need to continue to include Italy in the oncology allocation programme, since the price increases had been obtained. Specifically, this is mentioned in an internal correspondence between Mr. E and other managers of the Aspen group referring to the possibility to determine the drug quotas destined to the single wholesalers (*"we would predetermine the maximum sales that could be made to a particular wholesaler over a defined period (month/quarter)"*): to this regard, Mr. E observed that it was no longer necessary to use the "stock allocation" system, since the prices of Cosmos drugs had been aligned with those of the other European Countries: "[omissis]."<sup>107</sup>

123. From several exchanges of e-mails found during inspections at APIL's premises, it is clear that in Spain, at the end of 2014, Aspen suspended the commercialisation of the drugs under exam at the prices in force – while waiting for the definition of a price agreement with the Spanish authorities – nonetheless supplying Spanish patients through packages sent from other European countries, among which Italy,<sup>108</sup> but applying the prices in force in France. In fact, in an e-mail dated 31 October 2014, sent from Mr. D to Mr. E, it is possible to read: *"we currently supply Spain with foreign packs for the oncological range due to low prices in Spain" (a) "The plan is that from 1st January 2015 we will continue to sell only 'foreign packs' but at the French price level, i.e. lowest in EU. This will be subject to AGEMED [editor's note, the Spanish pharmaceutical regulatory authority] accepting [...] if [...] they reject the FR price we will cease supply. ...assuming there is no issue, we will supply."*<sup>109</sup>

124. In the same correspondence, Aspen's Spanish person of reference asked what to do with the quantitative of product already reserved to the Spanish market, which however was not going to be placed on the market given the suspension of the reimbursement of said drugs; the answer received was to donate or destroy said packages: *"As for the Spanish packs we cannot sell these as we've suspended reimbursement [...] need to retain them for emergencies only [...] donate or destroy."* [emphasis added].<sup>110</sup>

125. As regards the provenance of the foreign packages, it is clear from the mentioned correspondence that Aspen managed the product reallocation toward the Spanish market by reassigning quantitatives previously destined to other Countries, questioning on the possibility to incur in a stock-out (shortage) in the "donating" countries, and evaluating the economic advantage of the various options. The mentioned exchange of e-mails concerning Spain's supply through "foreign packs" indicates Aspen's awareness and responsibility concerning the shortage of said products in the single national markets: *"for Italy we would go out of stock in January", "If we go out of stock in Italy, do we make more money if we sell in Spain as opposed to Italy"* [emphasis added] - *no, we will lose more money if we go out of stock in Italy [...]*.<sup>111</sup>

126. The suspension of supplies toward Spain and the shipping of quantities from other markets (among which Italy) was confirmed by Aspen in its brief.<sup>112</sup>

### **IV.3 ANALYSIS OF THE PRICES IMPOSED BY ASPEN**

#### **IV.3.1 Preliminary remarks on the methodology**

127. This section will identify the elements necessary to analyse the prices applied by Aspen for Cosmos drugs, starting in March 2014 - that is following the negotiation described under the previous par. IV.2 - with the aim to assess the unfairness of the prices under exam.

128. The analysis will be carried out through a methodology described hereafter, based on previous cases,<sup>113</sup> in line with what provided for by the European jurisprudence, according to which there is no single method established by law for carrying out said analysis.

129. Therefore, the aim is to establish whether the prices applied by Aspen in its dominant position can be considered abusive since the group exploited possibilities deriving from said position on the market to obtain commercial advantages applying excessive pricing, without any reasonable relationship with the economic value of the service provided.<sup>114</sup>

---

<sup>107</sup> [Cf. doc. 12.35 B.22.]

<sup>108</sup> [In the correspondence, the reallocation of quantities coming from the French market is considered, as well as those coming from Italy, the United Kingdom, Russia and the Netherlands. Cf. doc. 20.4.]

<sup>109</sup> [The preference indicated was to supply the Spanish market directly through quantitatives coming from France. However, in case of need or shortage of product in the French market, Aspen indicated that the quantitatives of foreign product could come from any EU country, but they were to be sold on the Spanish market with the price in force in France. Cf. doc.20.6.]

<sup>110</sup> [Cf. doc. 20.6.]

<sup>111</sup> [Cf. doc 20.4. ]

<sup>112</sup> [Doc. 213, § 70.]

<sup>113</sup> [Cf. Court of Justice, C-27/76, *United Brands Company and United Brands Continentaal BV against the Commission of the European Communities. Chiquita Bananas*, ruling of 14 February 1978; OSA, C-351/12, paragraph 88; C-52/07, *Kanal 5 and TV 4*; C-226/84, *British Leyland v. Commission*; C-26/75, *General Motors v Commission*; C-30/87, *Corinne Bodson against SA Pompes funèbres des régions libérées*; C-323/93, *Crespelle*; Commission, COMP/C-1/36.915 - *DeuCTShe Post AG – Interception of cross-border mail*; Commission, COMP/A.36.568/D3, *Scadlines Sverige AB v. Port of Helsingborg*.]

<sup>114</sup> [Cf. Court of Justice, C-27/76, *United Brands*, cit., paragraphs 249 and 250.]

Analogous conducts are currently object of investigation in parallel cases carried out by other competition authorities of the European Union, with reference to behaviours of other pharmaceutical companies and other products.<sup>115</sup>

130. First of all, it is necessary to establish the economic value of the service provided by the undertaking. Lacking a regulatory framework, it is deemed that said value must at least reflect a measure of the production costs borne by the undertaking to realise the good or provide the service.<sup>116</sup>

131. Therefore, the analysis of the prices applied by Aspen will be carried out through a two-phase procedure, corresponding to one of the methods applicable in order to establish whether a price is abusive. In particular, this section will establish whether there is an excessive disproportion between the cost actually borne for the production of the good and the actual price requested by the company. Should the outcomes of the analysis be positive, the following aim will be to ascertain whether, even in the light of a series of elements pertaining to the specific case, an unfair price was imposed.<sup>117</sup>

132. On the basis of other cases of excessive pricing, it is possible to establish that the disproportion of the price imposed must be assessed referring to the total costs borne by the undertaking for realising the product. Said costs include *in primis* variable direct costs (in the financial statements defined cost of sales or cost of goods sold - COGS) and a quota of fixed direct costs as well as a quota of indirect costs borne by the undertaking, deemed reasonably related to the production of the good under exam.<sup>118</sup>

133. It seems reasonable to add to the mentioned total costs born by the undertaking for realising the product a fair remuneration for the activity carried out. To this aim, various indicators of the undertaking's profitability can be considered, ranging from indexes of return on capital employed (ROI, ROE, ROCE, WACC)<sup>119</sup> to sales profitability rates (ROS, contribution margin).<sup>120</sup>

134. There are no quantitative thresholds or precise arithmetic relationships that define what the measure should be in the disproportion between prices and costs in order to be considered indicative of an abuse of exploitation. The assessment of the unfairness of the prices imposed is to be carried out keeping into account the circumstances of the actual case and the absence of "reasonableness" in the relationship between price and economic value of the product, in the light of the specificities of the case, considering possible elements capable of affecting the total value of the service provided.

135. By analysing said elements, it is possible to draw conclusions concerning the reasonableness (or unreasonableness) of the disproportion existing between the price actually applied and the total economic value of the products and, therefore, price unfairness.<sup>121</sup>

136. There are various elements that can be considered to this end, on the basis of their capability to affect the economic value of the service provided. Therefore, the analysis can take into consideration:

---

<sup>115</sup> [UK Competition & Markets Authority, case EC/9742-13, *Unfair pricing for phenytoin sodium capsules in the United Kingdom*, case ongoing (Statement of objections sent to the parties Pfizer and Flynn Pharma on 6 August 2015). Moreover, press news highlight that such behaviours were adopted by U.S. companies, showing a strategy that takes on characteristics similar to speculations typical of the financial sector. With reference to the U.S. "Gilead case" see, *inter alia*, the comment of the Wall Street Journal: <http://www.wsj.com/articles/gilead-sciences-down-on-discounting-news-1423070093>, last accessed on 23 September 2016. With reference to said case, it is hereby reminded what AIFA's position was in the editorial by the General Manager Luca Pani, *Dall'Etica del profitto al profitto dell'Etica: sofosbuvir come esempio di farmaci dal costo insostenibile, una sfida drammatica per i sistemi sanitari e un rischio morale per l'industria*, 18 July 2014, p. 2 (<http://www.agenziafarmaco.gov.it/it/content/dall%E2%80%99etica-delprofitto-al-profitto-dell'etica-sofosbuvir-come-esempio-di-farmaci-dal-coste-i>, last accessed on 2 September 2016).]

<sup>116</sup> [Cf. Court of Justice, *United Brands*, cit., paragraph 251: "Moreover, this disproportion could be assessed objectively on the basis of a comparison between the product sales price and production cost, a comparison which would allow to identify the size of the profit margin." It is hereby highlighted that under paragraph 254 the determination of the disproportion is deemed possible despite: "[...] the non-negligible and sometimes enormous difficulties that the determination of production costs implies. Sometimes, it is necessary to make a discretionary division between indirect percentages and general expenses, since said costs can differ remarkably depending on company's size, object, complexity, territorial scope of action, product uniformity or variety, the number of subsidiaries and their mutual relationships [...]".]

<sup>117</sup> [Cf. Court of Justice, *C-27/76, United Brands*, cit., paragraph 252. ]

<sup>118</sup> [Direct costs are the costs borne expressly to realise a specific product. This item is opposed to indirect costs, borne by the company with reference to more product lines and therefore not directly ascribable to the profit and loss account of the single good (for example, administrative expenses). While direct costs are immediately ascribable to the related product, indirect costs need to be divided among the various product lines for which they are borne through an "allocation key," that is a criterion for giving quotas of said costs to the various lines.

In turn, direct costs can be distinguished between variable direct cost and fixed direct cost: the former depend on the volumes of goods produced (typically reflected in the cost item called "cost of sales," including by way of example, the costs of the raw materials used in the production), while the latter is borne regardless of the quantities realised (for example, costs for purchasing the trademark of a product). This implies that fixed direct costs are usually allocated over several years (amortisation) and ascribed pro quota in the profitability analysis of a product.]

<sup>119</sup> [ROI, Return on Investment; ROE, Return on Equity; ROCE, Return on Capital Employed; WACC, Weighted Average Cost of Capital.]

<sup>120</sup> [ROS, Return on Sales. ]

<sup>121</sup> [Cf. Court of Justice, *United Brands*, cit., paragraph 250. On the matter see also other rulings of the EU Court of Justice: *OSA*, C-351/12, paragraph 88; *Kanal 5 and TV 4*, C-52/07, paragraph 28; *British Leyland v Commission*, C-226/84, paragraph 25-33 and *General Motors v Commission*, C-26/75, paragraph 12.]

- 1) a comparison between the prices imposed by the undertaking and prices applied previously or in other markets by the same undertaking for the same products or with reference to prices of competing drugs and the amount of the resulting gap;
- 2) with reference to demand, qualitative factors not directly reflected in the costs borne by the undertaking such as, for example, improvements of the product from a therapeutic viewpoint (pharmaceutical formulation, chemical composition, dosage, packaging, etc.) or from a distribution viewpoint and, more in general, the level of service provided to purchasers, that can affect the economic value;
- 3) the presence or absence of economic justifications for the price levels imposed;
- 4) with reference to supply, the presence of a potential competitive pressure capable of conditioning the undertaking's behaviour in defining the price;
- 5) the nature of the product, with particular reference to the existence of substitutes;
- 6) the undertaking's characteristics, with particular reference to possible research activities carried out and the bearing of related investments in innovation.

137. Therefore, any possible qualitative elements not reflected directly in production costs totally ascribed to calculating the price-cost disproportion and specific to the case under exam, shall be evaluated in the second phase of the analysis.

On the other hand, it is hereby specified that, given the peculiar nature of the products under exam (life-saving drugs), the determination of their value cannot be carried out taking into consideration consumers' willingness to pay: the willingness to pay for life-saving drugs lacking therapeutic alternatives can only tend to infinite, potentially justifying any price increase.

138. All this being said concerning the criteria generally adopted to assess pricing unfairness, in order to evaluate the disproportion between prices and total costs in the case at hand, two methodologies of analysis were used: the first, consisted in analysing the disproportion between prices and costs measured through the gross contribution margin of each single Cosmos drug; the second, examined the disproportion between the prices applied and the costs borne by Aspen measuring the difference between profits and the so-called cost plus, that is direct costs added up to a quota of indirect costs attributed to products and a measure of the undertaking's profitability.

This is in line with the economic doctrine and jurisprudence concerning excessive pricing, according to which – lacking a regulatory framework for defining the abusiveness of the prices imposed – the parallel use of several calculation and analysis methodologies is viewed favourably.

139. The prices taken into consideration as basis for the calculation, both in the first and in the second methodologies proposed hereafter, are to be considered net of discounts imposed by law and of the distribution margin recognised by Aspen to LFM, since the turnover values used in the analysis (coming from the company's internal accounting) are lower than the specific turnovers communicated by the Party, already net of the overall set of said items.<sup>122</sup> This is true both for prices before increases, and for those following the increases being discussed.

140. It is hereby mentioned that the hypotheses on which the economic analysis is based are favourable to the undertaking, as it will be specified hereafter (cf. *infra*, par. IV.3.3 B).

141. Table No. 4 shows an extrapolation of the data present in APHL's financial statement, which will be used in the analysis that follows.

---

<sup>122</sup> [The values considered for calculating the disproportion were identified in document 44.24 ("Market P&L"). For each product, said values result lower than the values of the specific turnover communicated by Aspen (cf. doc. 125), corresponding to the turnovers registered by Aspen in the transfer of the products to LFM. Concerning said turnovers, the Party clarified that they are net of the commission recognised to the distributor (doc. 194). In addition, even wanting to consider the percentage of discount provided for by law recognised by Aspen to the distributor (for obligatory discounts, pay back, claw back and contribution for settling the overrunning of the threshold of hospital pharmaceutical expenditure), the turnovers communicated by the Party exceed those used for calculating the disproportion (cf. doc. 225).]

**Table No. 4: Data of APHL's consolidated financial statement** (values in millions of €)\*

APHL'S CONSOLIDATED FINANCIAL STATEMENT		June 2014	June 2015
PQ	PROFITS	2,079	2,654
CDQ	DIRECT COSTS (COST OF SALES)	(1,112)	(1,387)
<b>PQ - CDQ = MC</b>	<b>CONTRIBUTION MARGIN</b>	<b>966</b>	<b>1,268</b>
a)	SELLING AND DISTRIBUTION EXPENSES	(310)	(413)
b)	ADMINISTRATIVE EXPENSES	(116)	(207)
c)	OTHER OPERATING EXPENSES	(66)	(67)
d)	OTHER OPERATING INCOME	49	40
<b>MOL = MC - a) - b) - c) + d)</b>	<b>GROSS OPERATING MARGIN</b>	<b>523</b>	<b>621</b>
e)	INVESTMENT INCOME	20	28
f)	FINANCING COSTS	(95)	(169)
<b>PROFIT before taxes = MOL + e) - f)</b>	<b>RESULT BEFORE TAXES</b>	<b>448</b>	<b>480</b>

Source: APHL's Annual financial statements 2014 and 2015

\* APHL's financial statements are provided in South-African rand currency (ZAR). To these values, ZAR/€ exchange rates were applied as indicated by Aspen in its integrated report.

#### IV.3.2 Analysis of the contribution margin

##### A) Methodology

142. The first methodology assesses the disproportion between prices and costs, measured through the gross contribution margin<sup>123</sup> provided by each product and comparing said margin with the total fixed and indirect costs borne by Aspen, as identified in APHL's financial statement.<sup>124</sup> The ratio applied to determine the contribution margin of each Cosmos drug is as follows:

**PQ - CDQ = MC** where:

P = unit price

Q = quantity

CD = unit direct cost

MC = contribution margin

<sup>123</sup> [The gross contribution margin, also called gross margin (gross profit, if positive), represents the difference between the net value of sales and the cost of goods sold (COGS) of a company's specific product or set of products. In analytical (or managerial) accounting it represents a tool for assessing the contribution that a specific product (or in general the specific business management) provides to the net business income (profit/loss of fiscal year). Generally speaking, the profitability analysis of a specific product is based on percentage indexes, more easily comparable among the various product lines. In particular, within the scope of the so-called "ratio analysis," the absolute value of the contribution margin and of the cost of goods sold is put in relationship with the sales value, obtaining two percentage indexes - the "gross profit %" (contribution margin in the percentage of sales) and "COGS%" (cost of goods sold in the percentage of sales). It is hereby observed that the contribution margin expressed as the percentage of sales (gross margin %) represents the 100% complement of the cost of goods sold in relationship to the sales (COGS %), being:

<sup>124</sup> [Cf. supra note 117.]

The profits of the single Cosmos product (PQ) less the direct cost ascribed to the same (CDQ, corresponding to the cost of sales, also called COGS, cost of goods sold) results in a contribution margin to the net business income (MC). This margin, calculated as the percentage of sales resulting from APHL's financial statement, (MC%, comprised between 30% and 70% of sales) is compared with the indirect costs which are also in the percentage of sales (CI%, equal to 30% of sales) to establish the excessive marginality guaranteed by each Cosmos product.

**MC% - CI% = EXC** where:

CI = indirect costs

EXC = excess

143. This subtraction gave a positive result for each Cosmos drug even before discussing the intervention of price increases.

*B) Application to the case at hand*

144. Before proceeding with the profitability analysis of the single Cosmos products, it is worth highlighting that the products under exam in their whole generated a positive contribution to Aspen's income even before the renegotiation of prices, measured by the gross contribution margin.

In fact, the Sales and Distribution agreement entered into in 2009 between Glaxo and AGI indicates that Cosmos products at worldwide level produced a total gross margin of about [1-50] million British pounds (about [1-50] million di €).<sup>125</sup> For the Italian market, schedule 7 annexed to the agreement - called "Value by product by market" - indicates that, at the moment of the transfer of the product portfolio, the set of five drugs under exam produced a gross margin of [500,000-600,000] British pounds (about [600,000-700,000] €).<sup>126</sup> Said data were confirmed by the Party.<sup>127</sup>

145. The spreadsheets acquired during the inspections at APIL's premises show the Profit and Loss Account data (P&L) of each relevant product, that can be filtered for each national market. Said data highlight, with particular reference to Italy, that Cosmos drugs produced a positive contribution margin equal to at least [20-30]% of the sales value.<sup>128</sup>

Table no. 5 shows the extrapolation of said data and, in particular, the sales value or sales profit (PQ), the cost of goods sold (COGS) corresponding to direct costs (CDQ) and, by subtraction, the contribution margin (gross profit) of the products object of the investigation with reference to year 2013 and to the Italian market (also MC). Moreover, the lower part of the table shows the gross profit % and the COGS%, that is the analysis of the profitability ratios of said products.

146. On the basis of said information, it is clear that for Italy, in 2013 - that is before the renegotiation of the prices considered herein - the contribution margin for the business income of the drugs under exam, MC%, was comprised between [20-30]% for Leukeran and about [70-80]% for Purinethol.<sup>129</sup> As a consequence, for said products the cost of sales expressed as percentage of sales, CD%, was between [70-80]% and [30-40]% (cf. last line of Table 5).

**Table n. 5 – Analytical accounting: contribution margin of Aspen's products before the renegotiation**

Valori in € 000				
MERCATO	ITALIA		ANNO 2013	
<u>PRODOTTO</u>	ALKERAN / MELPHALAN	LANVIS / THIOGUANINE	LEUKERAN / CHLORAMBUCIL	PURINETHOL / MERCAPTOPURINE
RICAVI DI VENDITA	[200-250]	[60-70]	[90-100]	[200-250]
COSTO DEL VENDUTO (COGS)	[(50-100)]	[(1-50)]	[(50-100)]	[(50-100)]
MARGINE LORDO DI CONTRIBUZIONE (GROSS PROFIT)	[100-150]	[1-50]	[1-50]	[100-150]
<u>RATIO ANALYSIS</u>				
GROSS PROFIT %	[50-60]%	[30-40]%	[20-30]%	[60-70]%
COGS %	[40-50]%	[60-70]%	[70-80]%	[30-40]%

<sup>125</sup> [The annual average exchange rate in 2008 was equal to 0.796285 €/£.]

<sup>126</sup> [Cf. doc. 20.3.]

<sup>127</sup> [Cf. doc. 106, p. 4.]

<sup>128</sup> [Doc. 44.24.]

<sup>129</sup> [Cf. doc. 44.24. ]

147. All the above information needs to be compared with what emerges from Aspen's financial statements closed at June 2014.<sup>130</sup> As explained hereafter, said comparison highlights:

i) first of all, that the profitability of Aspen's products in Italy resulted in average in line with the profitability generated by the group's entire activity;

ii) secondly, that none of Cosmos products (in Italy) generated a contribution below *[omissis]* the sales value.

148. In fact, Aspen's 2014 financial statements indicate that the contribution margin (gross profit) as the percentage of sales of the entire group resulted equal to 46.5%. The net income of the fiscal year in relation to sales ("Net Profit (net of tax)/sales") of the entire Aspen group for fiscal year 2014 was equal to 17%.

The subtraction between the two percentage values, (46.5% - 17%) equal to 30%, results in all of the costs and the fixed and indirect costs (extra compared to the costs of factors used to realise the product sold) which are to be subtracted from the contribution margin to obtain the net income of the fiscal year.

149. This means that a gross contribution margin equal to 30%, given the structure of costs prior to the price renegotiation, corresponded to a net income equal to zero. Therefore, this contribution value can be considered a sort of balance or of "lower limit" in the profitability analysis of the single products of the Aspen group.

150. The meaning of the threshold identified seems confirmed by a series of spreadsheets collected at APIL's premises, containing various data concerning the profit and loss account for Cosmos products in the various geographical markets in which said drugs are sold. One spreadsheet in particular, titled "*FinDD-COGS*," distinguishes (by using various colours) the product/country combinations depending on whether the cost of goods sold (COGS) is above or below *[70-80]*% of sales.<sup>131</sup>

This internal analysis is in line with the above consideration, on the basis of which a contribution margin equal to *[20-30]*% of sales (therefore, costs of goods sold equal to *[70-80]*%) represents a sort of balance in the assessment of the profitability of the single product, for each geographical market: for Italy, as indicated in Table n. 5, second last line, for year 2013, this threshold *[omissis]*.

151. Therefore, the products object of the inquiry, in year 2013 - that is, before the price increases discussed herein - contributed in a measure comprised between *[20-30]*% and *[70-80]*% to the net income of the Aspen group (or, symmetrically, entailed costs of goods sold not above *[70-80]*% of sales). That is in line with the average contribution sales values resulting from the group's last financial statement before the price increase under exam and consistent with a positive net income of the fiscal year.

152. Using the formulation indicated under the previous paragraph par. IV.3.2 A), the conclusions expressed above can be formalised as follows. For each Cosmos product in 2013:

$$\text{MCI \%} \geq [20-30]\%$$

Therefore, given the measure of indirect costs expressed as percentage of the group's sales *[omissis]* equal to 30% (**CI% = 30%**), each product assured at least a balance between profits and total costs, already before the price increase under discussion, that is:

$$\text{EXC} = \text{MCI \%} - \text{CI\%} \geq 0$$

153. It is important to highlight that the measure of indirect costs identified above also includes the balance of capital management and taxes (items of cost that do not fall within the determination of the operating margin), since 30% correspond to the difference between the gross contribution margin and the net income of the fiscal year (already cleared from interests and taxes).

154. To conclude, in order to assess the disproportion between prices and costs, the analysis described above implies that the prices of Cosmos drugs applied by Aspen in Italy already before the negotiation with AIFA were above the economic value of said products, calculated according to the total direct and indirect costs borne by Aspen for their realisation.

155. This entails that, once the increases decided by AIFA were applied (from +300% to +1,500%) to the sales profits of Cosmos drugs in March 2014, Aspen's profits from selling Cosmos drugs in Italy remarkably exceeded the total costs ascribable to the products under exam, at least in equal percentage.

#### **IV.3.3 Analysis of the profits and total costs ascribable to Cosmos drugs**

##### *A) Methodology*

156. The second methodology proposed consists in examining the disproportion between the prices applied and the costs borne by Aspen for Cosmos drugs according to the following ratio:

$$\text{PQ} - (\text{CDQ} + \alpha \text{CI} + \text{ROS}) = \text{EXC}$$

<sup>130</sup> *[Cf. Aspen' financial statement is available at <http://3u8n9x34n0y14cxsva1mzqsa.wpengine.netdna-cdn.com/wp-content/uploads/2014/05/Aspen-2014-AFS.pdf>, last accessed on 16 August 2016.]*

<sup>131</sup> *[Cf. doc. 44.6, spreadsheet "FinDD-COGS," column "P."]*

The value in parenthesis shall be called cost plus and is obtained by adding up direct costs (CDQ or cost of goods sold), the share of indirect costs ascribable to the product ( $\alpha$ CI) and the measure of the return on sales (ROS):

$$\text{cost plus} = (\text{CDQ} + \alpha\text{CI} + \text{ROS})$$

therefore:

$$\text{PQ} - \text{cost plus} = \text{EXC}$$

157. By subtracting cost plus from profits (PQ) the excess (EXC) is obtained of which the possible unreasonableness is to be evaluated. The measure of the deriving excess will be compared to the cost plus in order to obtain a percentage value (EXC%), invariant compared to the sales volumes and comparable with the results obtained in other cases of excessive pricing.

$$\text{EXC}/\text{cost plus \%} = \text{EXC\%}$$

*B) Application to the case at hand*

158. The economic analysis above described and carried out hereafter, is based on several assumptions, all aimed at protecting the Party's interests, as described hereafter.

- Pro quota attribution of direct costs: the holding's choice of consolidated financial statements

159. As mentioned, to establish the disproportion of a price compared to the economic value of the related product, it is necessary to consider not only the direct costs borne for production (cost of goods sold), but also a quota of the operating expenses faced by the company, not integrally ascribable to the product, for their horizontal nature, because concerning activities that involve more product lines or more geographical markets.

160. Considering the competition authorities' discretionary power to identify indirect costs to allocate, *pro quota*, to the profit and loss account of the single products examined with reference to the disproportion between prices and costs and the "case by case" nature of said assessment, it was chosen to identify the source of the indirect costs to ascribe to Cosmos products in the data resulting from the consolidated financial statements of the South-African holding APHL, keeping into account the organisation of the Aspen group and the different business functions of the various undertakings (cf., *supra*, §§ 28, 29 and 30).

161. This choice is based on the fact that the Italian turnovers deriving from selling Cosmos products are registered at central level by the company AH in Dubai, controlled directly by the South-African holding APHL and do not "transit" in the financial statements of the group's European subsidiaries.

162. In fact, as clarified by the Party, as regards the selling of Cosmos products in Italy, Aspen adopts the so-called buy and sell distributive model, with the transfer of the products to the independent Italian distributor LFM that assumes the ownership (cf. *supra*, § 29).<sup>132</sup> Cosmos drugs destined to the Italian market are transferred directly from AH to LFM, which takes care of distributing and selling to the final customer.

163. Therefore, the European undertakings APIL, APTL and AI do not carry out a direct activity connected to the selling and distribution of Cosmos drugs on the Italian territory, unlike what occurs for other European markets in which Aspen sells Cosmos products through the so-called consignment model, that is giving the drugs to local distributors on a sale or return basis (cf. *supra*, § 29).

164. Consequently, the financial statements of the European subsidiaries reflect turnovers and costs deriving primarily from the direct commercialisation of Cosmos drugs in the countries in which the consignment model is implemented. Therefore, it would be wrong to carry out a specific allocation of the indirect costs of said companies with reference to the Italian market.

165. The business activities carried out at European level and ascribable to the Italian market for Cosmos drugs concern APIL's supply chain management and APTL's MA holding. These activities correspond to a fraction of the undertakings' profits and costs.<sup>133</sup>

However, also the costs borne by APIL and APTL for the activities just mentioned are registered in the consolidated financial statements of the South-African holding, which by definition consolidates all of the Aspen groups' activities.

166. The decision to identify the indirect costs to allocate to the Italian market in the data of the financial statement of the holding APHL protects the Party, as it entails the allocation of a quota of all the indirect costs borne by the Aspen group for its overall business, including the costs borne by the European subsidiaries.

- Determination of the allocation coefficient of indirect costs

---

<sup>132</sup> [The invoices related to the sales of Cosmos drugs are issued to LFM by AH (cf., by way of example, doc. 20.17.B.116 and doc. 17.B.133).]

<sup>133</sup> [Moreover, the data of APIL's and Aspen Italia's financial statements are available only starting from year 2014, that is from when the two companies started their activities in said fiscal year. ]

167. Once identified the indirect costs to be allocated *pro quota* to the single Cosmos products, it is necessary to define an allocation criterion, that is a principle according to which part of the indirect costs (distribution and sale expenses, other operating expenses) can be ascribed to the realisation of the single drug and therefore considered as an input in determining the economic value of the product.

168. On the basis of the accounting data available, it was chosen to use the cost of goods sold as allocation "driver" of indirect costs. This means that indirect costs that emerge from APHL's financial statements will be ascribed to Cosmos products for Italy according to a ratio deriving from the relationship between the specific cost of goods sold (COGS) of each Cosmos drug for the Italian market and the total cost of goods sold registered in the holding's financial statements. This ratio, called  $\alpha$ , will be multiplied by the items of indirect cost resulting from the same financial statements. This will allow to obtain the quota of said costs to ascribe to the single Cosmos drugs on the Italian market. This choice appears justified by a double motivation: (i) on the one hand, it seems reasonable to assume that indirect costs of a company affect the single products in a proportional measure to direct costs; (ii) secondly, direct costs borne for the production of a good appear the best value proxy of the inputs necessary for the realisation of the good, and therefore, the best candidate among the criteria usable for the *pro quota* allocation of indirect costs to said product. For each Cosmos product, therefore, the allocation coefficient will be established as follows:

$$\alpha_i = \frac{\text{COGS Product (s) Italy}}{\text{total COGS group}} = \frac{\text{CDQi}}{\text{total COGS group}}$$

The quota of the total indirect costs to ascribe to the drug (i) will therefore be established through the following ratio:

$$\text{CI}_i = \alpha_i (\text{total CI group})$$

169. In particular, the items of the financial statements allocated are as follows: "Selling and Distribution," "Administrative expenses" and "Other Operating Expenses," that is all indirect operating costs. Subtracting said costs from the gross contribution margin results in the operating management (Earnings before interests, taxes, depreciation and amortisation or EBIT) (cf. *infra*, Table No. 4).

#### - Remuneration rate of the business activity

170. As mentioned, the analysis of the disproportion between prices applied and costs borne by the dominant undertaking with the aim to establish the excessive burdensomeness of prices must duly consider a profitability margin for the company: it is in fact reasonable that the price applied for a specific product provides the company with a fair remuneration of its activity, it not being possible to assume that the same operates without the aim of a reasonable profit.

171. Therefore, a profitability measure shall be ascribed to the set of costs directly and indirectly ascribable to the product ( $\text{CDQi} + \alpha_i \text{CI}$ ). As mentioned, it is possible to identify various profitability indexes.

In the case at hand, it was chosen to apply a remuneration of the business activity measured by the Return on Sales (ROS).<sup>134</sup> The choice of said profitability indicator, instead of capital remuneration indexes (ROE, ROI, ROCE), is given by the nature of Aspen's activity: a pharmaceutical group mainly active in commercialising generic drugs or the so-called branded drugs (with a trademark), but developed by other companies. Consequently, under the Party's express admission, Aspen realises limited investments in research and development activities (cf., *infra*, § 195), particularly for Cosmos drugs.<sup>135</sup>

172. With specific reference to Cosmos drugs, these are not produced by Aspen, but by third companies (cf., *supra*, § 30): Aspen does not have tangible assets connected to the production of said drugs (production plants).

173. Basically, the activities carried out by the Aspen group in commercialising Cosmos drugs in Italy are limited to ordering, stocking and transferring the products to the external distributor LFM. Such activities do not require significant investments in tangible assets. Therefore, a measure of sales profitability appears to be the most significant index in examining the profitability of said products for the Italian market.

174. As regards the specific value of the return on sales to apply in the analysis, in a view of favour for the Party's interests, the application of a ROS was granted equal to 13%, which corresponds to the average return on sales rate realised in the two-year period 2013-2014 by the two major pharmaceutical companies active in the sector of production of generic drugs at worldwide level.<sup>136</sup>

#### - Ex ante and ex post analyses

175. With reference to the methodology applied, it is hereby clarified that the excessive burdensomeness analysis was carried out starting from the internal accounting data of 2013 and already mentioned under § 145. Said data, corresponding to internal profitability analyses (business analytical accounting) – not contested by the Party – show,

<sup>134</sup> [The ROS is given by the ratio between operating earnings and net profits.]

<sup>135</sup> [In fact, as mentioned, they are products purchased from GSK, with a patent expired decades ago. Cf. doc. 213, § 17. ]

<sup>136</sup> [Teva Pharmaceuticals and Mylan.]

for each Cosmos product, the value of the specific profits (PQi), the cost of goods sold (CDQi, direct costs) and by subtraction the contribution margin (MCI) related to the period 2009-2013 for various markets, among which Italy. Therefore, in order to examine the disproportion between prices and costs of Cosmos products for the Italian market, the starting point was the 2013 data, determining the cost plus values for each product line (Alkeran, Leukeran, Purinethol and Tioguanine) related to the year that preceded the price increases decided by AIFA.<sup>137</sup> Therefore, the product profitability was measured prior to the price increases.

176. Since an analogous set of internal data related to the period following the price increases in Italy (decided at the end of March 2014) was not available, the exam of the Cosmos drugs *ex post* profitability (to the new prices applied by Aspen) was carried out by applying the following increases to the 2013 costs and profits values:

a) the sales profits were increased according to the price increase percentages established by AIFA's resolution of March 2014 upon the outcome of the negotiation (assuming the constancy of sales volumes);<sup>138</sup>

b) the direct cost items were increased in the same percentage resulting from the comparison between the consolidated financial statements of the first fiscal year following the price increases (June 2015) and the last financial statements before said increases (June 2014). In other words, it was assumed that the direct costs of Cosmos drugs for Italy increased in the same proportion of the costs of Aspen's entire group, that is 25%.

It is to be considered that said assumption is favourable for the company since the cost of sales (direct costs) of said drugs, identified by the internal accounting data, had a constant trend between 2009 and 2013, not justifying any increase between 2013 and 2014;<sup>139</sup>

c) as regards the indirect cost items to ascribe to the single Cosmos products for the Italian market, the data taken as reference were those present in the group's first financial statements following the price increases examined (that is the financial statement of fiscal year closed at June 2015).

*B.1) The disproportion of prices compared to costs: analysis of the so-called cost plus (operating margin plus a congruous remuneration of the business activity)*

177. The following tables show for each Cosmos product the results deriving from the analysis carried out.

Table n. 6 indicates the profit and loss account of each product prior to price increases, highlighting the contribution margin (**MCI**) and the operating margin (**EBIT i**).

Said results are obtained as a subtraction between the specific turnovers of each Cosmos product (**PQi**) realised in Italy before the negotiation, the specific direct costs (cost of sales, **CDQi**) and the quota of the various total indirect costs ascribed to the single product: this attribution, as mentioned, is based on allocation coefficients **ai** established as ratio between the specific cost of sales and the group's total cost of sales.

178. The data on profits (**PQi**) and cost of sales (**CDQi**) for each Cosmos product in the Italian market, before the price renegotiation (2013), are evident in the company's internal accounting (spreadsheet "Market P&L").<sup>140</sup> The cost item CDQi represents the costs directly ascribable to the product, corresponding to the so-called cost of sales.

179. It is hereby specified that the measure of the direct costs ascribed in the calculation (**CDQi**), corresponding to the cost of goods sold (COGS), does not include the amortisation of the expenses borne by Aspen for purchasing the marketing rights of said products, that is the trademarks. This element of cost, that the Party quantified in the total amount of [300-400] million dollars for the whole global market – specifying not to have at disposal the division of said amount per product and country<sup>141</sup> – is reflected in the holding's financial statement item "Other operating expenses," therefore treated as an indirect cost, as inferable by the group's Accounting Policies.<sup>142</sup> Therefore, this

---

<sup>137</sup> [It is hereby reminded that the information present in the internal accounting document used for the analysis – besides being object for accessing the Parties' acts – was contested by Aspen during the preliminary hearing of 7 May 2015, in which the representatives of the group were asked to clarify the content of the document (doc. 97).]

<sup>138</sup> [The percentage of price increase applied to Alkeran is given by the average of the percentage increases decided for the two specialty drugs, Alkeran in tablets and Alkeran by infusion.]

<sup>139</sup> [Moreover, the comparison between the holding's financial statement of June 2015 and that of June 2014 indicates that the total direct costs of the Aspen group (cost of goods sold) increased from one year to another due to an effect of volumes and not to an effect of price. In fact, the ratio cost of sales/profits remained constant (equal to 53%) in the two fiscal years, indicating that the percentage increase of said cost component from one year to the other was due to increases in volumes of total sales. In other words, the unit average cost of sales remains constant between the two fiscal years: consequently, to allow a 25% increase of the cost of sales specific for Cosmos products for Italy represents an assumption in the company's pure interest, not required by the factual data.]

<sup>140</sup> [Doc. 44.24.]

<sup>141</sup> [Cf. doc. 97, p. 4 and doc. 106, § 15.]

<sup>142</sup> [Cf. page 23 of the 2015 Annual Financial Statements of the Aspen group, available online at the address <http://3u8n9x34n0y14cxsva1mzqsa.wpengine.netdna-cdn.com/wp-content/uploads/2014/05/Aspen-Annual-Financial-Statements-2015.pdf>, last accessed on 16 August 2016. Under the item "Intangible assets" it is possible to read: "Amortisation is included in other operating expenses in the statement of comprehensive income." In the same section, under the item "Intellectual property," the criterion for inserting the financial statements and the amortisation of the expenses borne for purchasing trademarks and licenses is specified: "Expenditure on [...] trademarks, [...] licences [...] is capitalized. [...] intellectual property is recognised at cost and amortised on a straight-line basis over their estimated useful lives, which ranged from one to 40 years during the financial year."]

element of cost is reflected in the profit and loss account of Cosmos products as quota of the holding's indirect costs ascribed to the single drugs.

Tabella n. 6 - Conto economico prodotti Cosmos 2013 (valori in €)					
DESCRIZIONE	FORMULA	PURINETHOL	LEUKERAN	ALKERAN	TIOGUANINA
Ricavi specifici	$PQ_i$	[200.000-250.000]	[90.000-100.000]	[200.000-250.000]	[60.000-70.000]
Costi diretti specifici	$CDQ_i$	[60.000-70.000]	[70.000-80.000]	[90.000-100.000]	[30.000-40.000]
Margine di contribuzione lorda	$MC_i = PQ_i - CDQ_i$				
chiave di allocazione costi indiretti	$\alpha_i = CDQ_i / CDQ \text{ totali}$	[0-0,010%]	[0-0,010]	[0-0,010%]	[0-0,010%]
Allocazione costi indiretti	$CI_i = \alpha_i \times CI \text{ totali}$				
	- Selling and distribution	[10.000-20.000]	[10.000-20.000]	[20.000-30.000]	[10.000-20.000]
	- Administrative expenses	[5.000-10.000]	[5.000-10.000]	[10.000-20.000]	[5.000-10.000]
	- Other operating expenses	[0-5.000]	[0-5.000]	[5.000-10.000]	[0-5.000]
Margine operativo	$EBIT_i = MC_i - CI_i$	[100.000-150.000]	- [0-5000]	[70.000-80.000]	[5.000-10.000]

fonte: elaborazioni Agcm su dati dell'impresa

180. The group's quota of total indirect costs identified in Table n. 4 to ascribe to each Cosmos product was established multiplying the total indirect costs prior to price renegotiation, *ex ante* CI (financial statements 2014), by the allocation coefficients  $\alpha_i$  shown in Table n. 6.

181. Table n. 7 represents the profit and loss account of the single Cosmos products for Italy following price increases. Therefore, Table n. 7 highlights the same items shown in Table n. 6, updated on the basis of the occurred increases. In particular:

i) the sales profits were increased according to the percentages of price increases of Cosmos products object of the proceedings (ranging from 300% to 1,500%);

ii) the direct costs were established applying to the *ex ante* costs the percentage increase identified for the same cost item between the fiscal year closed at June 2014 and the one closed at June 2015, as highlighted by APhL's financial statements;<sup>143</sup> hence, the *ex post* cost of sales of each Cosmos product was established (**CDQi ex post**), in order to compare it with the profits valued to the new prices applied by Aspen (**PQi ex post**);<sup>144</sup>

iii) the indirect costs (**CIi ex post**) were established as quota of the total indirect costs deriving from APhL's first financial statements after the negotiation (financial statements June 2015).

<sup>143</sup> [The choice of the mentioned fiscal years is based on the fact that the price increases of Cosmos drugs took place at the end of March 2014 and were applied reasonably at least starting from the second half of said year: the closing of APhL's fiscal year in the month of June implies that the last financial statement not showing said increases is the one related to the fiscal year closed June 2014.]

<sup>144</sup> [It is hereby reminded that this assumption is absolutely protective for the company, since the data of the financial statement do not highlight increases of cost of sales due to price. Therefore, the unit cost of sales should remain constant from one year to another, not justifying increases of total costs, sales volumes being equal. Table n. 7 highlights the increase of profits specific in the Italian market, consequent to price increases (starting from the sales volumes). ]

**Tabella n. 7 - Conto economico prodotti Cosmos ex post (valori in €)**

DESCRIZIONE	FORMULA	PURINETHOL	LEUKERAN	ALKERAN	TIOGUANINA
Ricavi specifici dopo l'aumento	$PQ_i \text{ ex post} = PQ_i \times (1 + \Delta P\%)$	[1.100.000-1.200.000]	[1.200.000-1.300.000]	[2.200.000-2.300.000]	[200.000-250.000]
Costi diretti specifici dopo l'aumento	$CDQ_i \text{ ex post} = CDQ_i \times (1 + \Delta CD \text{ totali } \%)$	[70.000-80.000]	[80.000-90.000]	[100.000-150.000]	[40.000-50.000]
Margine di contribuzione lorda dopo l'aumento	$MC_i \text{ ex post} = PQ_i \text{ ex post} - CDQ_i \text{ ex post}$	[1.000.000-1.100.000]	[1.100.000-1.200.000]	[2.100.000-2.200.000]	[150.000-200.000]
chiave di allocazione costi indiretti	$\alpha_i = CDQ_i / CDQ \text{ totali}$	[0-0,010%]	[0-0,010%]	[0-0,010%]	[0-0,010%]
Allocazione costi indiretti dopo l'aumento	$CI_i \text{ ex post} = \alpha_i \times CI \text{ totali ex post}$				
	- Selling and distribution	[20.000-30.000]	[20.000 -30.000]	[30.000-40.000]	[10.000-20.000]
	- Administrative expenses	[10.000-20.000]	[10.000-20.000]	[10.000-20.000]	[0-10.000]
	- Other operating expenses	[0-5.000]	[0-5.000]	[5.000-10.000]	[0-5.000]
Margine operativo dopo l'aumento	$EBIT_i \text{ ex post} = MC_i \text{ ex post} - Cii \text{ ex post}$	[1.000.000-1.100.000]	[1.100.000-1.200.000]	[2.100.000-2.200.000]	[150.000-200.000]
fonte: elaborazioni Agcm su dati dell'impresa					

182. In Table n. 8 the value of the so-called cost plus was established for each Cosmos product, before and after price increases, according to the ratio as follows:

$$\text{cost plus } i = CDQ_i + \alpha_i CI + ROS_i$$

Therefore, the cost plus for each product results from adding up direct costs and the quota of indirect costs shown in Table n. 6 and n. 7, as well as a remuneration for the company's activity measured by a ROS equal to 13%, in line with the average results achieved by the two major companies of generic drugs at worldwide level.

The latter value is established by applying this percentage to the specific profits of the products shown in Table n. 6 and n. 7.

**Tabella n. 8 - Determinazione del cost plus prima e dopo gli aumenti di prezzo (valori in €)**

DESCRIZIONE	FORMULA	PURINETHOL	LEUKERAN	ALKERAN	TIOGUANINA
Return on sales 2013	$ROS \text{ 2013} = ROS \text{ 13\%} \times PQ_i$	[20.000-30.000]	[10.000-20.000]	[20.000-30.000]	[0-10.000]
Return on sales ex post	$ROS \text{ ex post} = ROS \text{ 13\%} \times PQ_i \text{ ex post}$	[100.000-150.000]	[150.000-200.000]	[250.000-300.000]	[30.000-40.000]
cost plus 2013	$CDQ_i + \alpha_i CI + ROS \text{ 2013}$	[100.000-150.000]	[100.000-150.000]	[150.000-200.000]	[60.000-70.000]
cost plus ex post	$CDQ_i \text{ ex post} + \alpha_i CI_i \text{ ex post} + ROS \text{ ex post}$	[250.000-300.000]	[250.000-300.000]	[450.000-500.000]	[90.000-100.000]
fonte: elaborazioni Agcm su dati dell'impresa					

183. In table n. 9, on the basis of the data provided in Tables n. 6, 7 and 8, the excess of the profits of each drug is processed, before and after price increases, with reference to the cost plus, according to the formula:

$$PQ - \text{cost plus} = \text{EXC}$$

Table n. 9 also highlights the values of the subtraction between profits and costs in the percentage of the cost plus, according to the ratio:

$$\text{EXC \%} = \text{EXC} / \text{cost plus \%}$$

As mentioned, the determination of the percentage of the excess makes the conclusions of the analysis unvaried with reference to sales volumes, and allows the comparison with various analyses of price unfairness carried out in previous cases.

Tabella n. 9 - Determinazione dell'eccesso sul <i>cost plus</i> prima e dopo gli aumenti di prezzo (valori in €)					
DESCRIZIONE	FORMULA	PURINETHOL	LEUKERAN	ALKERAN	TIOGUANINA
Eccesso dei prezzi sul <i>cost plus</i> prima degli aumenti	$PQ_i - \text{cost plus} = EXC_i$	[80.000-90.000]	[da -10.000 a -20.000]	[50.000-60.000]	[da -200 a -300]
Eccesso dei prezzi sul <i>cost plus</i> dopo gli aumenti	$PQ_i \text{ ex post} - \text{cost plus ex post} = EXC_i \text{ ex post}$	[850.000-900.000]	[950.000-1.000.000]	[1.800.000-1.900.000]	[100.000-150.000]
Eccesso in percentuale del <i>cost plus</i> prima degli aumenti	$EXC_i \% = EXC_i / \text{cost plus}_i$	[70-80%]	[da -20 a -10%]	[20-30%]	[da -5 a 0%]
Eccesso in percentuale del <i>cost plus</i> dopo gli aumenti	$EXC_i \% \text{ ex post} = EXC_i \text{ ex post} / \text{cost plus}_i \text{ ex post}$	[300-350%]	[300-350%]	[350-400%]	[100-150%]
fonte: elaborazioni Agcm su dati dell'impresa					

184. On the basis of what highlighted above for some Cosmos products (namely Alkeran and Purinethol), even before the application of the new prices, Aspen registered a high difference between profits and total costs equal to [20-30]% and [70-80]%, keeping into account a 13% return on sales.

More significantly, the new prices applied in Italy by Aspen for Cosmos drugs upon the outcomes of the negotiation with AIFA produced a relevant gap of profits over costs ascribable to the realisation of the single drugs (including a congruous remuneration margin). This excess of total costs (cost plus) shows values comprised between [100-150]% and [350-400]% (cf. last line of Table n. 9).

185. Although deeming that, in the case at hand, Aspen's investments in the trademarks do not necessarily need to be considered as relevant costs, they were included in the analysis carried out as indirect costs, even against the Party's lack of arguments on the division of said expense.<sup>145</sup> In order to highlight how a different treatment of said investments in the analysis would not change the conclusions reached with reference to the disproportion between prices and costs, the excess over cost plus was calculated also under a different hypothesis of costs for purchasing Cosmos products trademarks from GSK even more favourably to the Party, that is considering this item of cost as fixed direct costs (contrarily to what assumed in the rules for writing the group's financial statements, cf. *supra*, § 179) and thus ascribing the investments at hand in a direct way to the profit and loss account of each drug, rather than as a share of the group's indirect costs.

186. To this end, the costs for purchasing Cosmos trademarks were estimated considering the Italian market, on the basis of the sole indications given by the Party. As mentioned under § 179, the Party was not able to provide information on the total amount spent per country for purchasing said rights from GSK.<sup>146</sup>

In any case, Aspen stated that the amount paid in purchasing Cosmos trademarks corresponded to four times the profits realised for said products at the moment of the purchase.<sup>147</sup> On the basis of this indication the related expense borne by Aspen in 2009 was estimated with reference to each drug for the Italian market.

187. Following, an annual amortisation quota of the expense identified was calculated, on the basis of an estimated useful life of the drugs at the moment of purchase (2009) equal to 20 years. This assumption is consistent:

- with Aspen's accounting policies (cf. *supra*, note 145);
- with the characteristics of the drugs under exam, that have proven their validity and therapeutic unreplacability for more than 60 years and well beyond the expiry of the patent, with perspectives of future use in the treatment of the pathologies which they target.

188. Table n. 10 indicates the mentioned information and, in particular, the item "trademark amortisation quota" calculated on the basis of the method described above, that is:

#### **4 x PQ<sub>i</sub> = Cost of the products' trademark i)**

#### **Annual amortisation quota of trademarks = Cost of the products' trademarks i)/20 years**

Table n. 10 also highlights the result of the analysis in terms of excess over cost plus, in this second calculation hypothesis. The conclusions of the analysis do not change significantly even considering this hypothesis of greater favour for the Party: in fact, the new excess percentages range from [100-150]% to [300-350]%, compared to the previous range [100-150]% - [350-400]% (cf. Table n. 9).

<sup>145</sup> [Cf. doc. 97, p. 4; doc. 106, § 15; doc. 116, annex 7.]

<sup>146</sup> [Cf. doc. 106, §§ 15 and 16.]

<sup>147</sup> [Doc. 172, annex 1, § 75. ]

**Tabella n. 10 - Determinazione dell'eccesso sul cost plus con attribuzione diretta ammortamento marchi (valori in €)**

DESCRIZIONE	FORMULA	PURINETHOL	LEUKERAN	ALKERAN	TIOGUANINA
quota ammortamento marchi prodotto i	$\text{amm. marchi}_i = 4 \times \text{PQ}_i / 20 \text{ anni}$	[50.000-60.000]	[30.000-40.000]	[60.000-70.000]	[10.000-20.000]
cost plus ex post con ammortamento costo marchi	$\text{CDQ}_i + \alpha_i \text{CI} + \text{ROS} + \text{amm. Marchi}_i$	[300.000-350.000]	[300.000-350.000]	[500.000-550.000]	[100.000-150.000]
Eccesso dei prezzi sul cost plus	$\text{PQ}_i - \text{cost plus}_i = \text{EXC}_i$	[800.000-850.000]	[900.000-950.000]	[1.700.000-1.800.000]	[100.000-150.000]
Eccesso in percentuale del cost plus con ammortamento marchi	$\text{EXC}_i \% = \text{EXC}_i / \text{cost plus}_i \%$	[250-300%]	[250-300%]	[300-350%]	[100-150%]
fonte: elaborazioni Agcm su dati dell'impresa					

#### IV.3.4 Further elements useful to evaluate the unfairness of the prices imposed by Aspen

189. The analysis carried out in the previous two sections – on the basis of the two different calculation methodologies described in the preliminary remarks – allowed to highlight how the new prices imposed by Aspen, upon the outcomes of the renegotiation with AIFA, result to be disproportionate with reference to the overall costs actually borne by the undertaking. The second phase of the test consists in evaluating whether said prices result “*lacking any reasonable ratio*” with reference to the economic value of the service provided, and therefore unfair pursuant to article 102, letter a), of the TFEU in the light of the characteristics of the case at hand. Postponing the assessment of the price unfairness of Cosmos drugs to the following section, this section is devoted to listing further elements – together with the disproportion just mentioned – that will be used for assessing said price unfairness, that is:

- the comparison between new and old prices;
- the absence of economic justifications for an increase of such proportion;
- possible qualitative factors related to the products;
- the nature of the products object of the exam;
- the characteristics and business model of the Aspen group;
- the increase of expenses for the public healthcare.

190. Always with the aim to assess the unfairness of the prices imposed by Aspen – and however in a concessive view for the company – a comparison will be carried out between the profits guaranteed to the group by each Cosmos drug against the investment borne for purchasing the related trademarks and the average return of the capital in the sector of generic drugs.<sup>148</sup>

191. This analysis highlights the internal investment return rate (IRR) for each Cosmos product ranging between [20-30]% and [30-40]%.<sup>149</sup> When comparing the initial investment with the profit flows corresponding to excessive pricing compared to costs (net of the sales margin recognised to the Party), the return percentages reached over the capital invested range from [10-20]% to [30-40]%.<sup>150</sup>

**Tabella n. 11 - Determinazione del tasso interno di rendimento dell'investimento nei farmaci Cosmos per il mercato italiano**

DESCRIZIONE	PURINETHOL	LEUKERAN	ALKERAN	TIOGUANINA
Valore iniziale investimento in trademarks	[1.000.000-1.100.000]	[700.000-750.000]	[1.300.000-1.400.000]	[300.000-350.000]
Cash flow annuale netto 2010-2014 (Margine = Eccesso incluso ROS 13%)	[100.000-150.000]	[da -2000 a -1000]	[70.000-80.000]	[7.000-8.000]
Cash flow annuale netto 2015-2029 (Margine = Eccesso incluso ROS 13%)	[1.000.000-1.100.000]	[1.100.000-1.200.000]	[2.100.000-2.200.000]	[150.000-200.000]
<b>TIR (Margine = Eccesso incluso ROS 13%)</b>	<b>[30-40%]</b>	<b>[30-40%]</b>	<b>[30-40%]</b>	<b>[20-30%]</b>
Cash flow annuale netto 2010-2014 (Margine = Eccesso senza ROS 13%)	[80.000-90.000]	[da -20.000 a -10.000]	[50.000-60.000]	[da -1.000 a 0]
Cash flow annuale netto 2015-2029 (Margine = Eccesso senza ROS 13%)	[850.000-900.000]	[950.000-1.000.000]	[1.800.000-1.900.000]	[100.000-150.000]
<b>TIR (Margine = Eccesso senza ROS 13%)</b>	<b>[20-30%]</b>	<b>[30-40%]</b>	<b>[30-40%]</b>	<b>[10-20%]</b>
fonte: elaborazioni Agcm su dati dell'impresa				

<sup>148</sup> [To this end, the following was considered:

- an initial investment (realised in 2009) corresponding to a multiple of four times the profits registered for the sales of said products in 2009, the year of their purchase from GSK, according to the criterion for determining the value of the trademarks indicated by Aspen;
- the investment generates a revenue in a timeframe of twenty years;
- cash flows deriving from the transfer of the drugs under exam corresponding to the margins observed under par. IV.3.3 B), that include both the ROS margin (13% of profits) and the excess of prices over total costs.]

<sup>149</sup> [Purinethol, [30-40]%; Alkeran, [30-40]%; Leukeran, [30-40]%; Tioguanine, [20-30].]

<sup>150</sup> [Purinethol, [20-30]%; Alkeran, [30-40]%; Leukeran, [30-40]%; Tioguanine, [10-20].]

192. These percentages can be compared with the average return on invested capital in the pharmaceutical sector, identified by various studies, from which it is clear that the pharmaceutical sector in its whole assures a weighted average cost of capital (WACC) equal to about 8%.<sup>151</sup>

## V. THE PARTIES' ARGUMENTS

### **THE ASPEN GROUP**

193. Aspen developed its defence mainly in the briefs of 2 February 2016<sup>152</sup> and 28 June 2016,<sup>153</sup> as well as in the final hearing of 5 July 2016.<sup>154</sup>

194. In said briefs and final hearing, the Party mainly contested:

- 1) several elements concerning the undertaking's correct carrying out of the negotiation and the regulatory framework in force;
- 2) the existence of several procedural flaws (preliminary juridical exceptions);
- 3) the definition of relevant markets;
- 4) the absence of a dominant position;
- 5) the qualification of Aspen's conduct as imposition of unfair prices.

Moreover, Aspen made several considerations on the seriousness of the conduct and the possible applicable sanction.

#### **V.1. OBJECTIONS CONCERNING THE NEGOTIATION**

195. In its preliminary remarks, the Group stated that its mission and business model in Europe and worldwide "consists in supplying safe quality drugs at accessible conditions, for the benefit of patients and healthcare systems, in terms of saving." Aspen's main activity is to supply generic drugs through their production and selling, while no research and development activities are carried out for the realisation of new drugs. Rather, Aspen invests in generating data concerning the period following the patent expiry, with the aim to support the existing therapeutic indications or develop new indications.

196. With reference to the purchase of the Cosmos portfolio from GSK, Aspen clarified that, before said transaction in 2009, it had no organisation and distribution network of its own in Europe and, therefore, it had to face launching costs. After purchasing Cosmos drugs, Aspen's position changed completely and was not at all comparable to GSK's: in fact, the Aspen group launched its activity in Europe and in Italy *ex nihilo*; moreover, the Cosmos drugs, rather than representing – as for GSK – "small and basically irrelevant niche products," constituted a significant and determining investment and, therefore, a fundamental component of its operations in Europe, including Italy.

197. Aspen specified that, following the transaction, the holding of the marketing authorisation of Cosmos products underwent various transfers, although the ownership always remained AGI's. In particular, not having its own organisational structure in the EU, Aspen initially identified a European company to which to entrust the commercialisation in the European markets, that is the French company *Laboratoires Genopharm*, and thus transferred the MA to said company. Following regulatory issues that involved the French company, the holding of the MA underwent further transfers. The MAs of the drugs examined were definitively transferred to the undertaking APTL upon AIFA's resolution of 5 March 2013.

198. Following the transaction with GSK, having the aim to continue satisfying a demand for drugs clearly not attractive for that group, Aspen launched a process for a price review of Cosmos products in the various European countries where the prices had not been modified since the 1960s. The Party deems said process fully legitimate, given the different business models adopted by the two pharmaceutical groups (GSK and Aspen) and the centrality of the Cosmos package in the range of products marketed by Aspen.

199. Aspen stated that Italy was one of the last countries in which the group launched a price review procedure, because the Italian procedure is longer than in other European countries. Concerning the point, the group highlighted that no objection was raised by the competent authorities and/or regulatory authorities of the pharmaceutical sector in other European Countries.

##### *V.1.1. The negotiation: ambiguities of the regulatory context and request to pass to Class C*

200. Aspen denied the adoption of a "specific strategy" aimed at excessive pricing, starting from the initial request to reclassify Cosmos drugs from the reimbursement Class A to Class C, at patients' expense.

201. The Party highlighted that the request to reclassify the drugs represents a right of the pharmaceutical company, regardless of the nature of the drug object of the request, and valid despite the absence of a specific provision applicable to the request to pass from Class A to Class C.<sup>155</sup>

---

<sup>151</sup> [Cf. <https://www.kpmg.com/DE/de/Documents/cost-of-capital-study-english-2014-kpmg.pdf>, last accessed on 2 September 2016; [http://pages.stern.nyu.edu/~adamodar/New\\_Home\\_Page/datafile/wacc.htm](http://pages.stern.nyu.edu/~adamodar/New_Home_Page/datafile/wacc.htm), last accessed on 2 September 2016.]

<sup>152</sup> [Doc. 172, annex 1.]

<sup>153</sup> [Doc. 213 and annexes.]

<sup>154</sup> [Doc. 220.]

According to the group, the regulatory framework applicable to the procedures for classifying and negotiating drug prices in force at the moment of the reclassification request submitted in April 2013, was also characterised by a certain ambiguity.

202. In particular, according to Aspen's opinion, the Decreto Balduzzi had introduced changes in the laws of reference such to determine uncertainty concerning procedures for drug classification and reimbursement, in particular appointing AIFA to carry out an extraordinary review of the National Drug Code (eliminating from the Code possible obsolete drugs) and to introduce a temporary classification, called "non-negotiated Class C."

203. According to the Party, Aspen's drugs could have been considered "*drugs of new authorisation*" and, therefore, ascribable to the so-called "non-negotiated Class C" category (actually applicable only to drugs at their first introduction on the market), due to the fact that their prices had never been negotiated with AIFA according to the criteria established by CIPE Resolution No. 3/2001. In fact, said drugs had been marketed in Italy many years before the entering into force of the mentioned resolution and AIFA's actual constitution. Therefore, it was allegedly legitimate to apply for a reclassification in Class C.

204. Secondly, as mentioned, Decreto Balduzzi obliged AIFA to proceed with an extraordinary review of the Drug Code within 31 December 2015 (the so-called delisting procedure): three of the five Cosmos drugs (Purinethol, Leukeran and Myleran) had been included by AIFA in the list of drugs subject to evaluation for a possible *passing into Class C*. On the basis of the information collected by Mr. F, the evaluation of the possible delisting of said specialty drugs took place in a meeting held on 3 June 2013 by the CTS and in a plenary meeting held on 27 September 2013, both following the date of the drug reclassification requests submitted by Aspen to AIFA: basically, at the moment of the first reclassification request (April 2013), AIFA had not yet decided whether or not to maintain Cosmos drugs in the Drug Code (reimbursed drugs).

205. For the reasons highlighted above, Aspen deems that the reclassification request in Class C of the drugs under exam was justified by the ambiguity of the context and by an incomplete regulatory framework in force in April 2013, as well as by valid objective justifications for considering the Cosmos products "*obsolete and in principle susceptible and fit for being inserted in Class 'C.'*"

206. Moreover, to prove the legitimacy of the request to review the reimbursement class, Aspen observed that said request was in actual fact accepted by AIFA for the drug Myleran (that too belonging to Aspen's anticancer package), because considered "obsolete" by the CTS.

207. With reference to its non-provision of economic information and data to support the price review request, Aspen stated that no regulatory measure was applicable to the reclassification requests of Cosmos products, since CIPE Resolution No. 3/2001 regulates cases for reclassification requests in Class A or H, but not those related to the reclassification from A to C: therefore, on the basis of the laws in force, Aspen had no obligation to provide the mentioned data.

According to Aspen, in fact, the dossier required by the mentioned resolution for drug reimbursement requests cannot be applied to reclassification requests. Therefore, information concerning product costs, investments and export data required under point 8 of said dossier, are not allegedly necessary in Class C reclassification requests. In order to support said conclusion, Aspen observed that, on the basis of the "*Guidelines for classification and prices*" published by AIFA on its website, producers intending "to modify the reimbursement regime" are required to produce information as provided for by points from No. 1 to No. 7 of the dossier. Aspen added that AIFA did not require any further information apart from data concerning the international comparison of prices and consumption of the drugs under exam.

208. In conclusion, on the basis of Aspen's arguments, the drug reclassification request submitted in April 2013 is to be intended as "*an initial contact with AIFA,*" formulated on the basis of a situation of genuine uncertainty given by an ambiguous regulatory framework, "*with no intention to transfer the prices of the anticancer drugs entirely onto patients.*"<sup>156</sup>

209. Moreover, the company stated that the circumstance according to which the products had been defined as essential in the reclassification requests, on the basis of the data provided by Aspen to AIFA, does not necessarily imply that the requesting party had to be aware – when submitting the first request – of the therapeutic irreplaceability of the products, since said evaluation falls within the competence of AIFA's committee of haematologists. According to Aspen's opinion, the fact of indicating the drugs as "essential" in reports submitted by the Party at the beginning of the negotiation was not intended as "irreplaceable," but as wanting to highlight the "inexpensiveness" of the medicine: drugs are "*essential in the measure in which they have a very contained price; in fact, the term essential is used in the sense of useful because inexpensive.*"<sup>157</sup>

---

<sup>155</sup> [According to Aspen, the request to negotiate the "07" reimbursement class is always admissible, as regulated by AIFA's Guidelines.]

<sup>156</sup> [Cf. doc. 121.]

<sup>157</sup> [Doc. 213, § 161.]

210. For the Party, the documentation used to prove the existence of an alleged strategic plan carried out by Aspen in the negotiation is unreliable, because it consists in an exchange of e-mails that contain "clear boasting" phrases of Aspen's external consultant.<sup>158</sup>

211. In conclusion, the Class C reclassification request cannot be considered a tool for making pressure in the negotiation, as Aspen had no way of knowing whether AIFA would have decided to keep the Cosmos drugs in the National Drug Code. Moreover, the Group highlighted that the statements made by AIFA's representatives during the hearing before the Offices concerning the exceptional and aggressive aspects of Aspen's initial request are to be considered mere opinions.<sup>159</sup> The same is valid for the statement of AIFA's CTS President referred by the external consultant, according to whom Aspen's request was to be considered "lacking the requisites normally required to approve a price increase."<sup>160</sup> Against the latter consideration, there is AIFA's satisfaction expressed in the official statement of 11 July 2014, highlighting the alignment of the new Italian prices of Cosmos drugs to the "lower prices applied in Europe."

#### V.1.2. Oncology allocation programme and the shortage of Cosmos drugs: no threat to suspend supply

212. Aspen contested the content of the report submitted by Altroconsumo to AIFA on 10 September 2014, concerning the shortage of Leukeran, Alkeran and Purinethol between February and March 2014. In fact, consumers' reports collected by the Association concern the period between Aspen's agreement with AIFA in January 2014 and the publication of the related measure on 31 March 2014. For Aspen there would have been no logic to run out of supply deliberately in the period following the agreement.

213. With reference to the so-called "oncology allocation program" managed by Aspen, the group stated that the sole function of this tool is to assure a constant supply of products on the market and not to limit supplies for strategic purposes.

214. With reference to the report submitted by the pharmacy in the North-East of the Country,<sup>161</sup> Aspen stated that the non-supply of the drugs was due to its distributor LFM, that acted in contrast with article 105, par. 4, of D.Lgs. No. 219/2006 (which obliges distributors to provide medicines within 12 hours from the pharmacist's request). Aspen's availability to collaborate with the Regulator is proven by the undertaking's commitment during the meeting of 22 January 2014 to increase by 10% the supply of products in shortage, so as to solve the episodes of reported lack and to assure continuity in supplying patients.

215. Aspen highlighted that the temporary shortage of Cosmos products in the Italian market had occurred also before the negotiation with AIFA, since 2012, as proven by the documents filed. The above mentioned events concerning the transfer of the holding of the MA contributed toward the temporary lack of the drugs.<sup>162</sup>

In fact, Aspen referred of periodical problems in the production of Cosmos drugs that did not involve only Italy, always in the negotiation period, however without providing further details or documents concerning said production problems.

216. Basically, according to Aspen, the shortage of Cosmos products that occurred in the period of negotiation is not ascribable to the company and cannot be interpreted as a tool for placing negotiation pressure on AIFA. On the contrary, said shortage was due to: organisational problems of the distributor LFM; [omissis]; the physiological flow of a parallel marketing of Cosmos products toward countries in which the new prices had already been applied.

217. Aspen contested that the letter sent to AIFA in October 2013 (cf. *supra*, § 96) contained a threat to suspend the direct supply of Cosmos drugs in Italy. The reference to a direct supply suspension (without an MA withdrawal) is to be interpreted as Aspen's availability to guarantee the supply to Italian patients through a "Named patient-based programme," assuring the supply of a quantitative of medicine coming from abroad at prices applied in the foreign countries of provenance, on the basis of doctors' requests. Aspen highlighted that the MA holder can legitimately decide to suspend supplies also for marketing reasons, pursuant to article 34 of D.Lgs. No. 219/2006 and for a limited period of three years, defining with the regulatory authority the supply of the necessary foreign packs.

218. To this regard, Aspen contested the similarity of the "Named patient-based programme" with the compassionate use of drugs, as stated by AIFA in its reply to the Offices' requests for information. The Group stated that it would have temporarily followed the procedure provided for by AIFA on its website for cases of drug supply exhaustion, on the basis of which hospitals or doctors ask AIFA the authorisation to import on individual basis and at prices applied in the foreign countries; then, "at the right moment," it would have launched the procedure pursuant to D.M. of 11 May

---

<sup>158</sup> [Cf. doc. 213, § 40.]

<sup>159</sup> [Cf. doc. 84.]

<sup>160</sup> [Cf. doc. 213, § 47.]

<sup>161</sup> [Cf. doc. 21.]

<sup>162</sup> [To this regard, Aspen reminded that, in answer to a Parliamentary interrogation of 31 July 2012, the Minister of Health referred to the suspension of Genopharm's activities ordered by the French authorities and the consequent problems in the transfer of the MAs as the cause for the temporary shortage of Purinethol in Italy. From the document it is clear that there was shortage of Alkeran also in June 2012.]

2001, according to which the drugs imported are transferred at Italian prices and reimbursed by the SSN (cf. *supra*, § 61).

## V.2. PROCEDURAL EXCEPTIONS

219. Aspen contested procedural flaws in the inspections carried out in Ireland.

220. The Party mentioned the lack of an authorisation issued by the Authority to carry out inspections at APIL in Dublin, infringing D.P.R. No. 217/1998, and the consequent illegitimate use of documents collected at APIL's premises. Aspen deems that the Authority should have issued an inspection measure in order for the Irish Competition Authority to carry out inspections.

221. According to Aspen, a further procedural flaw concerns the notice of the extension of the procedure against APIL, allegedly not complying with the international provision for notifying the procedure launched against APTL, as it submitted the notice directly to its legal representative appointed by the same for the proceedings.

222. Still with reference to the inspections carried out at APIL, Aspen stated that the collection of a hard drive belonging to APIL's General Manager (Mr. A) during inspections infringed article 8 of CEDU and articles 7 and 8 of the Charter of Fundamental Rights. In fact, according to the Party, said collection concerned material not only extraneous to the object of the proceedings, but it was collected without previously viewing its content, since filtered only afterwards by the CCPC when transmitting the documents to the Italian Authority pursuant to article 12 of Regulation No. 1/2003.

223. Another procedural exception concerns the infringement of the principles of reasonableness and fairness of the administrative procedure by sending two Communications on the Results of the Investigation (Comunicazione delle Risultanze Istruttorie - CRI) with two charges for totally different antitrust infringements, that is a "*progressive*" antitrust infringement and "*by attempts*." In fact, according to Aspen, instead of simply specifying and clarifying the juridical qualification of the alleged illicit conduct charged against Aspen, the Authority's Offices carried out a totally new analysis in the second CRI on the basis of data and information at their disposal from the very beginning of the proceedings and, in any case, way before the formulation of the first CRI. In particular, the Offices allegedly abandoned the thesis of abuse of the law, focusing on the new type of abuse and juridical qualification as "*excessive pricing*."

## V.3. EXCEPTIONS CONCERNING THE DEFINITION OF RELEVANT MARKETS

224. Aspen deems that the Authority exceedingly restricted the competitive scope of action by adopting a definition of relevant market that coincides with the basic products of a specific active ingredient (level ATC5), in contrast with the European and national pharmaceutical precedents, in which the market has never been restricted beyond level ATC4, corresponding to the therapeutic class.

The Party deems that said reconstruction is based on an analysis of the replaceability of the drugs object of the investigation based on non-detriment elements. In particular, Aspen deems that excessive importance was given to the form of drug administration, distinguishing from products with the same therapeutic indications and mechanisms of action.

225. With reference to the existence of products capable of replacing Cosmos drugs, the economic brief filed by Aspen<sup>163</sup> states that the Offices' analysis is flawed by an error in the approach, known as "reverse cellophane fallacy."<sup>164</sup> the replaceability analysis between the various products on the market took as reference an initial price significantly below the competitive level, considering that the prices of Cosmos drugs had remained unvaried from the 1960s to 2014. As a consequence, the preferences of patients, doctors, AIFA and the SSN towards the various products on the market had been formed on the basis of totally distorted prices (given the ridiculously low price of Cosmos drugs compared to that of drugs with different active ingredients). This allegedly made the existing therapeutic substitutes of Cosmos drugs economically irreplaceable, with the consequent wrong definition of relevant markets.

226. Aspen's economic brief provides an empirical analysis of the variation in sales volumes of Cosmos products following the price increase, highlighting an average percentage drop equal to [30-40]%. This decrease allegedly highlights the presence of substitutive therapies.

Aspen complained that an analysis was not carried out for the counter-factual scenario in case of absence of Cosmos drugs in the Italian market. Therefore, the Authority did not demonstrate that: "[...] i) patients are not treated with competitive products via intravenous injection; ii) the competing producing companies are not able to substitute the production of tablets; iii) competitors do not sell drugs easily accessible at retail level (that is, through pharmacies instead of hospitals)."<sup>165</sup>

227. The briefs produced by the Party highlight that AIFA, GIMEMA and the oncologic-haematological experts contacted by Aspen confirmed, for each Cosmos drug, the existence on the market of products made of other molecules authorised for the treatment of the same pathologies treated by Cosmos drugs.

---

<sup>163</sup> [Doc. 213, annex 1.]

<sup>164</sup> [Cf. doc. 213, annex 1, p. 10.]

<sup>165</sup> [Cf. doc 213, § 152.]

228. Aspen stated that the documentation provided by AIFA proves that Cosmos drugs are used in various schemes of multiple chemotherapeutic combinations. Therefore, it could result difficult to identify therapeutic substitutes fully replaceable in terms of effectiveness and safety. According to Aspen, AIFA's statements highlight the indispensability identified only with reference to Purinethol in the treatment of ALL, while the use of the other drugs depends on patients' characteristics and age.<sup>166</sup> The Party stated that GIMEMA's position is not clear, since the association's representatives declared that "there are innovative drugs on the market based on different active ingredients but destined to the treatment of several pathologies treated by Aspen, that however cannot be considered replaceable with the latter. In fact, Aspen's drugs are used in specific populations of patients and in precise phases of the therapy."<sup>167</sup>

229. Therefore, the irreplaceability concerns specific groups of patients and precise stages of related diseases against the existence of substitutive drugs for treating the same pathologies. According to Aspen, AIFA's and GIMEMA's opinions highlight that Cosmos drugs are indispensable for several specific pathologies within the group of diseases treated by Cosmos drugs and with reference to specific stages of the diseases and specific groups of patients.

230. Moreover, also the independent opinions provided by two foreign experts and two "among the major Italian experts in haematology"<sup>168</sup> – already in part described in the section concerning relevant markets (cf. §§ 78 and following) – highlight, according to Aspen, a certain level of irreplaceability for "[...] at least some of the four products object of the proceedings [that] could be in a certain measure replaced by competing products in terms of therapeutic use and alternative protocols. [emphasis added]".<sup>169</sup>

231. The economic brief made use of the scientific opinions mentioned to identify the various pathologies for which Cosmos drugs are used. On the basis of said reconstruction, the economic brief distinguishes among therapeutic uses for which authorised marketed alternatives exist and uses for which Cosmos drugs are instead irreplaceable.

232. Following the logic of the so-called SSNIP test, only if the incidence of Cosmos drugs for the single therapeutic uses was very significant, the company would have maintained an actual autonomy in its price choices (absence of competitive pressure).<sup>170</sup> On the contrary, if the turnover of each Cosmos product is generated mainly by sales destined to therapeutic uses for which there are substitutes on the market (competitive restriction), the company is obliged to consider the effect of the loss of volumes deriving from a significant increase in the sales price.<sup>171</sup>

233. Therefore, the Party stated that the approach adopted by the Offices is incompatible with the European Commission's position expressed in the discussion paper of 2005 on the implementation of article 82 of ECT to

---

<sup>166</sup> [Cf. doc. 6.]

<sup>167</sup> [Doc. 94.]

<sup>168</sup> [Doc. 214, annexes 14, 15, 16 and 18. With reference to the single drugs, the Party (doc. 213, annex 1, p. 12 and following.) highlighted the following observations provided by specialists:

- LEUKERAN: the opinion of expert 1 highlights that the drug is the only substitute available for the treatment of CLL, and that the "mono-therapy with chlorambucil represents a key therapeutic modality acceptable in patients over 70 years old." With reference to Non-Hodgkin lymphomas, expert 1 observed that "although there are various therapeutic substitutes that do not require the use of Leukeran, the drug is still commonly used and there are no equivalent protocols between combinations containing Leukeran and others," and "while waiting for the introduction of Zydelig, the role of chlorambucil will very likely be resized, although with a relevant increase of costs;"

- ALKERAN TABLETS: as stated by expert 1, in the therapy of multiple myeloma, Alkeran can be validly replaced by bendamustine, but it is irreplaceable for particularly weak patients and for multidrug therapies that envisage the use of bortezomib and talidomide. To this regard, expert 2 observed that – for the weaker patients – "the diffusion of the use of lenalidomide, instead of talidomide, will improve the outcomes of elderly patients and it can be proposed as a drug substitute to melphalan [Alkeran]."

- ALKERAN INJECTIONS: the injectable formulation is irreplaceable because it is used in therapeutic programmes that envisage the use of single or double self-transplant, an approach consolidated worldwide (expert 1).

- TIOGUANINE: it does not play a relevant role in the treatment of acute myeloid leukaemia, since the use of this drug has become obsolete due to the availability of chemotherapeutic schemes that do not require its use, and the experimental protocols that include it, the effectiveness of the inclusion has not been proven (expert 1). As regards the treatment of acute lymphoblastic leukaemia, Tioguanine is present in about one third of the chemotherapeutic schemes, and there is no evidence of the superiority of a scheme over another. In other words, the schemes that envisage Tioguanine can be perfectly replaced with others.

- PURINETHOL: for the treatment of ALL, it was noticed that Purinethol plays an essential role, but only for maintenance therapies of adults and children (expert 1). No accredited protocols seem to exist envisaging the substitution of 6-mercaptopurine with other active ingredients. For the treatment of acute myeloid leukaemia, the use of Purinethol is instead obsolete. Expert 2 explained that, always for the treatment of acute lymphoblastic leukaemia and acute myeloid leukaemia, "recently, in patients suffering from APL at low or intermediate risk, the efficacy of a regime without chemotherapy has been proven based on arsenic trioxide (ATO) and retinoic acid (Lo Coco, 2013). In this scheme, a maintenance therapy with ATRA/6- MP/MTX does not appear necessary." Purinethol seems to remain irreplaceable for high risk patients.]

<sup>169</sup> [Doc. 213, § 158.]

<sup>170</sup> [Small but significant and non-transitory price increases, that is the hypothetical monopolist test carried out to determine the correct size of the relevant market, on the basis of the company's decisional autonomy in fixing sales prices of its own goods. ]

<sup>171</sup> [Following these general lines, Aspen made an estimate only for Leukeran concerning the incidence of the use of said drug in the treatment of Waldenstrom macroglobulinemia, for which there are no therapeutic substitutes, with reference to the total amount of sales volumes of the drug. Estimating (on the basis of hypotheses concerning the number of patients with said pathology and the average consumption of the drug) an incidence of said pathology equal to [10-20]% over the total sales, Aspen concluded that Leukeran is used [80-90]% mainly in the treatment of pathologies for which there are various alternative drugs: Aspen is not in the position to increase "its prices in full autonomy and independence, because most of the profits deriving from the increase of price would be more than compensated by the reduction of the turnover due to the loss of volumes to the advantage of the sales of competing drugs."]

exclusionary abuses (par. 18), according to which: *"in most of the cases it is not decisive that a certain group of consumers does not consider the products at issue as good substitutes. What matters is that a sufficiently large number of consumers deems that a product is a good substitute for the product provided by the company involved."*<sup>172</sup>

#### **V.4. EXCEPTIONS CONCERNING THE DOMINANT POSITION AND THE CONTENDIBILITY OF RELEVANT MARKETS**

234. As regards the contendibility of the markets, Aspen observed the absence in the market of entry barriers of any kind (patent, regulatory, strategic and economic) for the production and commercialisation of the four active ingredients involved in the proceedings. According to Aspen, the only barrier is represented by the exceedingly low prices, before negotiation: Aspen deems that the new prices negotiated cannot be considered exceedingly onerous since, given the absence of entry barriers, prices higher than the balancing ones would lead new entrants to produce and commercialise the molecules. Aspen concluded stating that the price increases obtained actually represent an incentive for generic drugs to enter the market, with predictable pro-competitive effects.

Since the patent expired in the 1960s, potential competitors can access the markets involved, as already occurred in other Countries, where generic drugs of Cosmos products are commercialised. In particular, Aspen mentioned the availability of a generic drug of Alkeran in the United States, of Purinethol in Turkey (produced by Kocak Farma) and in Spain (Silver Pharma), and of Tioguanine in the Netherlands (Teva Nederland B.V.).

235. Concerning the matter, Aspen estimates the average time necessary for a generic drug to enter the market around [25-30/35-40] months, a timeframe considered sufficiently brief for carrying out an actual competitive pressure.

236. As regards strategic barriers, Aspen deems that they were removed with the price increases of Cosmos drugs, since the prices applied previously represented a disincentive to enter the market, not allowing potential competitors to recover their investments in a satisfying timeframe.

237. With reference to economic barriers strictly speaking, Aspen estimates that a hypothetical entrant wanting to replicate the five Cosmos drugs would have to bear entry sunk costs comprised between [1-5 and 5-10] million dollars for the sole Italian market. In the case of a parallel entry in different geographical markets, the entry marginal cost would be that for registration expenses, equal to about [200,000-300,000] dollars for each additional country. The entry cost of a generic drug in Italy would be comprised between [50-60]% and [60-70]% of the gross turnover generated by Cosmos products valued to the new prices. Said incidence decreases with the increase of the geographical markets in which a generic drug company decides to commercialise its drug.

238. Aspen observed that any negotiation power boasted by the Group due to its dominance would however be counterbalanced by AIFA's countervailing buyer power, in its quality of Regulator - monopsonist, due to the negotiation role carried out by the single buyer, that is the SSN. Aspen's economic brief highlights that, if on the one hand AIFA had interest in finding a negotiation agreement with Aspen given the irreplaceability of the drugs under exam, on the other hand also Aspen was *"...in the position to have to enter into an agreement with AIFA, penalty the renunciation to commercialise drugs in Italy."*<sup>173</sup>

239. The absence of structural and strategic entry barriers impedes, according to the Party, to ascertain a dominant position of Aspen in the markets object of the proceedings.

#### **V.5. EXCEPTIONS CONCERNING THE CONDUCT CHARGED**

240. The Party contested the actual reasonableness of a case of unfair prices, stating – in line with several tests developed in economic literature – the inappropriateness of an antitrust intervention aimed at prosecuting this typology of abuse in a sector characterised by: *i)* absence of entry barriers; *ii)* presence of a Regulator and a single buyer; *iii)* high innovation rate of the pharmaceutical markets.

These peculiarities allegedly make the abuse of excessive pricing inadmissible.

241. Aspen stated that the previous MA holders commercialised the drugs at prices significantly below their economic value, due to the different nature of their business mission compared to that pursued by Aspen, or to the different weight attributed to the drugs in their range of products. In fact, the first MA holder, the Wellcome Foundation, being a no profit trust, was not guided by the interest to maximise profits; the second holder, GSK, considered Cosmos drugs as a source of marginal profits to the point that it was not worth facing the costs necessary for a price review.

On the contrary, Aspen purchased Cosmos drugs with a specific aim and even motivated by the observation that said drugs were commercialised at a price significantly lower than their economic value.

242. Moreover, from a comparison with the other European geographical markets, Aspen observed that the Italian prices are not statistically different or lower than those applied in other Countries.

243. With reference to the pricing of Cosmos products, the strong innovation rate that characterises the sector would justify Aspen's price fixing conducts according to a model known as Ramsey pricing. The latter envisages the

---

<sup>172</sup> [Doc. 213, annex 1, p. 15.]

<sup>173</sup> [Cf. doc. 213, annex 1, p. 20.]

determination of prices by a multiproduct innovative company based on the elasticity of demand for the various drugs, with the application of a higher mark up on costs for product lines under a less elastic demand.

In the case of Cosmos products, since demand elasticity for the drugs is equal to zero (or however very low) due to their life-saving nature, it would be individually and socially cost effective to increase the prices of said specialty drugs in a significant way: in the presence of high common fixed costs (typical condition of sectors with high innovation, such as the pharmaceutical one), socially cost effective prices are those that reflect the inversion of demand elasticity, allowing to recover common costs with the minimum impact on consumption choices (Ramsey pricing).

244. In this context, by deciding on the reasonableness of the pricing applied by Aspen, the Authority allegedly took the Regulator's place. In Italy, the mechanism for forming reimbursable drug prices envisages the interaction between the company and AIFA, subject in charge of balancing the company's power.

245. With reference to the analysis of the disproportion between prices and costs, Aspen deems, *in primis*, that the price increase and related impact identified on the SSN are totally overestimated by the Authority. In fact, the new prices of Cosmos drugs taken as reference in the calculation - that is, the prices to the public indicated in the Gazzetta Ufficiale - do not correspond to the actual prices paid by the SSN for the same drugs, being gross of the mandatory discounts deriving from the provisions applicable in the pharmaceutical sector, which are:

- i) a mandatory 5% discount on the price to the public for all drugs;
- ii) a further 5% discount on the two formulations of Alkeran due to the pay back mechanism;
- iii) an additional 1% discount for all Class A Cosmos drugs (with the exception of Alkeran in injectable formulation) on the related ex-factory price.

Moreover, the profits obtained by selling Cosmos drugs are further affected by the claw back mechanism in the measure of 1.83% of Aspen's total sales and by the further obligation to contribute pro quota to balancing the breaking of the pharmaceutical expenditure threshold.<sup>174</sup>

246. At the same time, the analysis carried out in the CRI did not consider the margin that Aspen recognises to LFM for its distribution activity (equal to about [10-15/15-20]%).<sup>175</sup>

247. This being said, the Party contested more in detail several of the assumptions that the CRI placed at the basis of the analysis, deeming in particular:

- 1) a wrong identification of a return on sales equal to only 13%. Aspen stated that an adequate remuneration should correspond to an average ROS achieved by the group equal to [15-20]%;
- 2) a wrong choice to allocate indirect costs on the basis of the incidence of direct costs. The Party deems preferable an allocation based on sales profits;
- 3) an excessive timeframe of 20 years decided arbitrarily by CRI as the time necessary to recover investments in trademarks. Aspen considers 10 years from the purchase as a more reasonable amortisation time based on the useful life of Cosmos drugs;
- 4) a wrong choice not to consider several items of cost and indirect profits, in particular: *other operating income, investment income and financing cost*.

248. On the basis of these alternative assumptions, Aspen concluded that the so-called "excess" of the new prices applied on cost plus is lower than the Offices' estimates, passing to values ranging between [60-70]% for Alkeran and [20-30]% for Tioguanine.

249. With reference to the relevance of said excess, Aspen contested the jurisprudential precedents examined in the CRI and, in particular, the percentage of 25% of the *DeuCTShe Post* case, because chosen arbitrarily. On the contrary, the analysis of the cases and applicable jurisprudence allegedly indicates the expediency to set said measure at a much higher level. Aspen recalled the *British Leyland* case in which the Court of Justice ascertained a 600% price increase, setting the threshold at 500%, and the *ITT Promedia* case in which the price increase amounted to 900%.

250. In the light of said precedents and on the basis of the estimate carried out on assumptions deemed more realistic and correct, the Party concluded that in no case the prices applied by Aspen can be considered "significantly" above the "competitive" benchmark: no solid juridical base can be identified to deem that a disproportion of prices compared to costs - that in no case is over [60-70]% according to the Party's estimates - would be such to satisfy the first part of the United Brands test.

251. With reference to the second part of the test - that is, the exam of the overall unfairness of the prices applied by Aspen - when estimating the economic value of the products object of the investigation, the Authority considered exclusively a "measure of production costs borne by the undertaking to realise the good or the service provided." In fact, the economic value of a good is established by many demand and supply factors that include, but do not exhaust,

---

<sup>174</sup> [The payback and clawback fall within the companies' co-participation policies in pharmaceutical expenses. In particular, the payback mechanism was established by the Financial Law of 2007 as alternative to the discount obliged by law equal to 5% on the price to the public, applied on the transfer to public structures of all the drugs in Class A and H. Opting for this mechanism, companies decide to pay the equivalent 5% on the price to the public, multiplied by the data of average consumption of the drug in the previous period. The company can choose whether to adhere to the payback system for each product on its price list. The clawback, introduced by art. 11, paragraph 6, of D.L. No. 78/2010, converted in Law No. 122/2010, consists in an amount paid by pharmaceutical companies to the Regions equal to 1.83% on the sales price to the public, net of VAT, for the drugs supplied in regime of agreed healthcare expenditure.]

<sup>175</sup> [Cf. doc. 213, § 268.]

production costs: the definition of the economic value cannot exempt from the usefulness that consumers obtain from goods and, more in general, from considering demand factors. By way of example, Aspen mentioned the gap between the price applied on a consumption good such as *[omissis]* and the costs underlying its production.

Taking into consideration alternative or complementary indicators of the economic value, Aspen concluded that the price of Cosmos products is in line with their economic value. These alternative indicators are: adjustment to the inflation of prices remained unvaried for 50 years; the comparison of drug prices at international level; demand elasticity; the non-entry of competitors in the markets involved following the increase of prices; the price setting mechanism.

252. However, Aspen deems unreasonable that prices dating back to the 1960s can be considered capable of mirroring the current economic value of the good to which they refer, since a simple adjustment based on the price index would lead to new prices even higher than those obtained following the negotiation with AIFA.

253. For these reasons, Aspen deems worthless the intra-time comparison among Cosmos drugs in the unfairness judgment, while stating that the Italian prices are not statistically different or lower than those applied in the other European markets, on the basis of an international comparison deemed more significant. Moreover, the various European Regulators accepted the reviews of the prices under exam, similarly to AIFA.

254. Aspen contested the claimed groundlessness of economic justifications for the price increase submitted to AIFA, which the Offices ascribed exclusively to the general indications mentioned in the letter dated October 2013 addressed to AIFA. On the contrary, the Party observed that the costs to be communicated to AIFA pursuant to the laws in force, not required by the Regulator, do not cover all the costs ascribable to the realisation of Cosmos drugs. Apart from production costs, it is necessary to consider the set of other costs (investments, establishment of operations in Europe, distribution structure) that justified the price increase.

In fact, the Party stated to have borne relevant costs in order to launch the commercialisation of Cosmos drugs in Europe, consisting in investments necessary for creating European branches: personnel costs, consultancies with experts and administrative costs for the management of the supply chain.

## **V.6 CONCERNING THE SANCTION**

255. With reference to the sanction established by the Offices, the Aspen group stated that, since it is a case of abuse of dominant position, the behaviour carried out cannot be considered a "serious infringement" of competition, because lacking secrecy and corresponding to a business behaviour totally legal for companies not in a dominant position.

256. With reference to the seriousness of the behaviour, Aspen contested that it can be based on the nature of the products, because it would be *"inadmissible to base on such indication the pretention that anticancer drugs are, for their own nature, products such to allow the Authority assess the seriousness of the infraction."*

257. According to Aspen, the level of the price increase must not affect the assessment of the effects of the infringement, because *"assessing the extent to which the new prices can damage the public expenditure and patients falls within AIFA's exclusive competences."*

Moreover, the Offices' estimate of the damage caused on the SSN is allegedly wrong because the impact of the price increases of Cosmos drugs on the pharmaceutical expenditure – indicated as a 500% increase – corresponded, instead, to an increase equal to only 360%, since said expenditure passed from € 1.9 million in 2013 to about € 7 million in 2014.

258. Aspen observed that, at the most, the duration of the behaviour covered the sole period of the negotiation with AIFA and it should not be extended to the entire period in which the new prices have been in force.

259. With reference to the sales value used in calculating the possible sanction, Aspen stated that the value to be taken as reference should not be the turnover that Aspen realised through the transfer of Cosmos products to the Italian distributor LFM. This because said datum does not necessarily coincide with the actual sales carried out by LFM to the public healthcare structures and pharmacies following the purchase from Aspen. The profits for selling Cosmos drugs to LFM, therefore, do not correspond to the SSN's actual annual expenditure.

260. Moreover, Aspen deems that the relevant turnover for the possible sanction is to be determined on the basis of the net prices applied by the group.

261. With reference to the entry fee and the overall size fee, Aspen deems that its business dimensions are much more reduced compared to other companies sanctioned by the Authority, namely Pfizer, Roche and Novartis, on which such adjustments were imposed when calculating the sanction (points 17 and 25 of the *"Guidelines on the modality for implementing the criteria for quantifying administrative fines imposed by the Authority implementing article 15, paragraph 1, of Law No. 287/90"*).

262. Lastly, Aspen deems that there is no aggravating circumstance in the case at hand and that, instead, a more extenuating circumstance should be applied, pursuant to point 23 of the Guidelines, that is: the effective collaboration with the Offices, especially considering the participation in the hearing of 7 May 2015 of all the managers summoned; the presence of a regulatory framework that allegedly favoured the ascertained infringement; Aspen's adoption, starting from 2013, of a specific antitrust compliance programme at worldwide level and adjusted to the European and national best practices. Said programme envisages the involvement of the management, the identification of the personnel responsible for the programme, monitoring and audit systems, the organisation of training activities. The training activities were integrated in May 2015 with relevant updates in order to adjust the programme to the needs of

the single Countries in which the multinational has its registered offices, promoting the implementation of “local face-to-face training” and the adjustment of the territorial programme to the specific business areas where the employees - addressees of the training - work.<sup>176</sup>

263. In conclusion, Aspen highlighted that the specific warning issued by the Offices could allegedly go beyond the Authority’s competences, affecting regulatory aspects falling exclusively within AIFA’s competence, as Regulator of the pharmaceutical sector having the task to establish the fair and reasonable level of drug prices reimbursable by the SSN.

### **ALTROCONSUMO**

264. The intervening association Altroconsumo, first of all stated to be in total agreement with the Offices’ reconstruction, and provided several clarifications in its brief and during the final hearing.<sup>177</sup>

265. In particular, with reference to the definition of the relevant markets, Altroconsumo highlighted the extreme importance of the form of administration of Cosmos drugs: the formulation in tablets allows its administration by mouth, while the other substitute drugs indicated by Aspen are administrated exclusively intravenously, at the hospital.

For a patient that has to follow a treatment over an extended period of time, it is not at all unimportant if said treatment is administrated at home in tablets or at the hospital intravenously, especially in the case of elderly patients or children.

266. Moreover, since the drugs under exam are integrally reimbursed by the SSN, patients-consumers and their doctors do not keep into account the price factor when choosing the drug, but exclusively other aspects, such as the lack of negative collateral effects, the low toxicity and how the drug is administrated.

267. Aspen’s market power is demonstrated by the size of the price increases achieved: AIFA was in no way able to balance Aspen’s monopolistic power.

268. As regards the behaviours deemed abusive, Altroconsumo considers irrelevant the circumstance according to which the prices had never been increased in the past, since what is charged against Aspen is not the price policy adopted in the last 40 years, but an abusive conduct that took place starting from the negotiation of the new prices with AIFA.

269. The Association deems that the reference to Aspen’s business model is fundamental for understanding the unfairness of the price increase imposed. In fact, Altroconsumo highlighted that there is a total lack of a socially useful investment by Aspen such to justify the extremely high price increase, since Aspen does not carry out any research and development effort whatsoever.

Aspen acted “*as a mere financial speculator,*” not contributing in any way whatsoever toward the improvement of the drugs developed by other companies, already widely experimented and established, neither in terms of treatments and/or research, nor from a marketing viewpoint. Aspen, in fact, did not bear any investments neither to improve the products, whose realisation is entrusted to third parties, nor for their marketing since “*these drugs are so well known that they sell on their own.*”<sup>178</sup>

Basically, according to Altroconsumo, the Party simply exploited the irreplaceability of Cosmos drugs with the aim to impose an absolutely unjustified price increase, which had the sole effect (economically sterile) to redistribute resources from the public treasury to the Aspen group.

## **VI. EVALUATIONS**

### **VI.1 PRELIMINARY MATTERS**

270. Preliminarily and in answer to the Party’s observations, it is hereby highlighted that, implementing the Authority’s resolution of 9 February 2016, with the second CRI notified to the Parties on 22 April 2016, the Offices simply specified the juridical qualification of the anticompetitive conduct already charged against Aspen in the first CRI of 30 October 2015. The latter highlighted the infringement of article 102, lett. a), TFUE and analysed the unfairness of the prices imposed by Aspen through the instrumental use of its right to renegotiate the prices of the drugs object of the proceedings.<sup>179</sup>

271. Moreover, Aspen rose a series of preliminary exceptions in part referred to factual elements – that will be discussed in the following sections - in part referred to alleged procedural flaws in the inspections carried out in Ireland.

To this regard, it is hereby specified that the Authority, with resolution of 19 November 2014, implementing article 22 of EC Regulation No. 1/2003, requested the collaboration of the Irish Competition Authority (Competition and Consumer Protection Commission – CCPC), as authority better positioned for collecting relevant proof for the ascertainment of

---

<sup>176</sup> [Doc. 213, annexes 26 A, 27, 28 and 29.]

<sup>177</sup> [Doc. 215 and 220.]

<sup>178</sup> [Cf. doc. 220.]

<sup>179</sup> [Cf. doc. 136, §§ 189 and following and § 234.]

possible conducts damaging competition carried out by Aspen Pharma Trading Limited on the Italian territory.<sup>180</sup> Under the same resolution, pursuant to article 12 of EC Regulation No. 1/2003, the Authority also asked CCPC to transmit “*all the elements found by fact or by law during inspections, so as to file them in the investigation report concerning the described conducts of Aspen Pharma Trading Limited.*”

272. Implementing the mentioned article 22, investigations are not authorised by the requesting national authority, but by the authority receiving the cooperation request. Consequently, in compliance with the Irish national regulation, the Judge of the Dublin Metropolitan District Court authorised, with specific search warrants, to carry out inspections at Aspen Pharma Trading Ltd. and at Aspen Pharma Ireland Ltd..<sup>181</sup> In fact, the Judge deemed that there were reasonable bases to believe that at said premises information could be found useful for the CCPC to carry out its functions, pursuant to the Competition and Consumer Protection Act 2014 and article 22, paragraph 1, of EC Regulation n.1/2003.

273. The CCPC deemed necessary for the Judge to issue a search warrant also for APIL’s premises, so as to satisfy the cooperation request formulated by the Italian Authority in the most effective and fruitful way possible, considering that APIL’s General Manager (Mr. A, who signed the correspondence with AIFA with reference to the negotiation under exam) was also APTL’s Director.

274. With reference to the alleged infringement of article 8 of the ECHR and of articles 7 and 8 of the Charter of Fundamental Rights, it is hereby highlighted as follows: First of all, the external hard drive collected and object of Aspen’s contestation belonged to APIL’s General Manager (APTL’s Director), directly involved in the strategy for raising the prices of Cosmos drugs in Italy, so much so to have signed several documents with which AIFA was asked to reclassify drugs and negotiate prices.<sup>182</sup> Secondly, said external hard drive was collected with APIL’s General Manager’s consent and after his confirmation that it contained information concerning the company’s activity. Thirdly, the CCPC selected the documentation in the hard drive using an indexation software (“EnCase”) through key words concerning the object of the case, identified on the basis of the provision launching the proceedings. Moreover, the collection of data concerning other products appears totally legitimate within a case of exceedingly burdensome prices, in which – as evident also from the analysis carried out in these proceedings – the data related to the costs of the entire business activity are taken into consideration. Lastly, all the documentation transmitted by the CCPC to the Authority was object of cross-examination with Aspen, the latter being allowed several times to access all acts filed, formulate requests for the restitution of documents and express its defence by filing briefs and participating in hearings. Therefore, the proceedings were carried out guaranteeing the right to defence and cross-examination.

275. With reference to the fact that the extension of the proceedings to APIL was notified to its legal representative instead of the company’s Irish premises (*supra* § 221), it is hereby observed that on 23 December 2014 the Authority received from Aspen’s law firm a copy of the proxy issued by APIL, with which domicile was elected at said law firm for the proceedings A480.<sup>183</sup> Therefore, the notification of the subjective extension procedure dated 20 February 2015 was correctly transmitted to the law firm where APIL had already elected domicile months before, pursuant to article 141 c.p.c..

## **VI.2 RELEVANT MARKETS**

276. As mentioned in paragraph IV.1, the relevant market of the products is defined at ATC5 level, corresponding to the single active ingredients of Aspen’s drugs, having proven – besides the lack of generic drugs (direct substitutes) – also the absence of indirect replaceability between Cosmos drugs and other specialty drugs available on the market, belonging to the same therapeutic chemical subgroup (ATC4) and authorised for the treatment of the same pathologies treated by Cosmos drugs.

277. It is essential to reassert that the definition of the competitive market of reference was based on the scientific conclusions of specialist doctors with reference to the *therapeutic* replaceability of Cosmos drugs. The absence of therapeutic replaceability with other drugs was ascertained by scientific bodies appointed for said purpose (AIFA’s technical body, the CTS) and confirmed by the independent opinion of expert oncologists of the Foundation GIMEMA, whose authoritativeness was expressly recognised by the Party.<sup>184</sup>

These reliable positions cannot be defined “*general opinions*,” as advanced by Aspen in its brief.<sup>185</sup>

278. The scientific evaluation concerning the absence of therapeutic replaceability precedes the exam concerning economic replaceability. In the absence of therapeutic replaceability it is almost impossible to make any economic comparison between Cosmos drugs and other products.

---

<sup>180</sup> [Doc. 19.]

<sup>181</sup> [Doc. 213, annex 14 and annex 15.]

<sup>182</sup> [Doc. 5, annex A, doc. 5, annex B. ]

<sup>183</sup> [Doc. 36.]

<sup>184</sup> [Doc. 94. With reference to the opinion of GIMEMA’s haematologists, it is hereby observed that even Aspen, in its brief, confirmed their authoritativeness and stated that the clinical protocols of said foundation are internationally and currently recognised (cf. doc. 213, § 155). ]

<sup>185</sup> [Cf. doc. 213, § 153.]

279. Therefore, Aspen's considerations concerning the so-called reverse cellophane fallacy are totally irrelevant. According to said considerations, the Authority allegedly circumscribed the markets excessively, on the basis of an exam of the economic replaceability flawed by the exceedingly low level of initial prices of Cosmos drugs: no analysis of price differences with other drugs was taken into consideration in defining the relevant markets.

280. In any case, Aspen's reasoning on the therapeutic replaceability between its drugs and substitutes present on the market and, in particular, the specialists' considerations filed by the company, are not conclusive with reference to Aspen's thesis. In fact, the opinions mention a theoretical replaceability ("they could in theory," "it would be in principle replaceable" [emphasis added]) and a partial replaceability ("[...] a couple of the four drugs," "in a certain measure" [emphasis added]) (cf. *supra*, § 230).

281. On the basis of AIFA's and GIMEMA's evaluations, the therapeutic irreplaceability between Cosmos drugs and the substitutes on the market at ATC4 level is due to several distinctive characteristics of the drugs under exam, making them the only specialty drugs usable in maintenance therapies at home for patients suffering from certain forms of leukaemia, and weaker patients (the elderly and children). These distinctive characteristics are:

i) the formulation in tablets of Aspen's drugs, that allows administration by mouth making them fit to be used in maintenance therapies at home. On the basis of said pharmaceutical formulation, Cosmos products are distributed at territorial pharmacies (Class A), with the exception of injectable Alkeran. This aspect further distinguishes them from the ATC4 substitutes administrated at hospitals (class H);<sup>186</sup>

ii) the high tolerability of Aspen's drugs, due to the lack of relevant collateral effects and to their long clinical experimentation (given the many years of presence on the market),<sup>187</sup> against a higher level of toxicity of the ATC4 substitutes. This aspect results to be particularly important given the nature of anticancer drugs, usually characterised by collateral effects, also particularly relevant.

282. For the injectable Alkeran (for hospital use), the irreplaceability derives from the fact that said drug is an essential component of clinical protocols for the therapy of severe pathologies, in combination with other drugs.

283. The relevance of how drugs are administered for assessing their therapeutic irreplaceability was highlighted also by Altroconsumo, that emphasised that it is not at all unimportant for a patient subject to a treatment over an extended period of time if the administration takes place at home by mouth or at the hospital intravenously, especially when patients are elderly or children (cf. *supra*, § 266).<sup>188</sup>

284. For the demand of said products, an extremely important role is played by the so-called "therapeutic continuity," that characterises the preferences of patients-consumers and corresponds to the patients' and prescribing doctors' tendency to maintain the therapy with the same drug even when there are therapeutic substitutes in commerce. This factor is even more important in oncologic therapies, given the presence of collateral effects, even significant, associated to anticancer drugs and the life-saving nature of said products, which also increases patients' psychological opposition to change.

285. In this context, the absence of relevant collateral effects characterising Cosmos drugs is a key factor for considering the irreplaceability of said products. In fact, the elective use of Cosmos drugs occurs precisely in the therapy of children and elderly people, that is weaker categories and more sensitive to the toxicity of oncologic drugs, regardless of the pathology treated, as stated by the oncologic experts heard during the proceedings, but also as inferable from the opinions of the Party's experts, that highlight as follows:

1) the pathologies for which Cosmos drugs are mainly used affect children and/or the elderly;

2) Cosmos drugs are used in the therapy of children and the elderly owing to their tolerability (cf. *supra*, §§ 70 and following).

286. AIRC's "Tumour Guide" confirms that the pathologies for which the specialty drugs under exam are mainly used affect principally the two categories of patients above mentioned, that is the elderly and children (cf. *supra*, § 73).

287. Therefore, the main element for analysing the replaceability of Cosmos drugs is not represented by the presence of other drugs destined to the treatment of the same pathology. Rather, the latter is represented by the circumstance according to which, for all the pathologies targeted, Cosmos drugs constitute the only products available in commerce for maintenance therapies at home for the weaker population, that is children and the elderly, for whom the administration by mouth of highly tolerable products is ideal.

288. Therefore, the Party's analysis concerning the incidence of therapeutic uses for which there are no substitutes within the total therapeutic uses authorised is irrelevant, although according to Aspen this aspect highlights the need to widen the relevant market.<sup>189</sup>

---

<sup>186</sup> [It is hereby reminded, in fact, that Aspen's drugs are included in Class A and therefore can be supplied by territorial pharmacies upon submission of medical prescription, while ATC4 drugs with other active ingredients are mostly included in Class H (for hospital use). Cf. doc. 94.]

<sup>187</sup> [On the matter, refer to the observations of GIMEMA's specialists in haematology (doc. 94 and, *supra*, §§ 70 and following).]

<sup>188</sup> [Doc. 215.]

<sup>189</sup> [Doc. 214, annex 1, p. 15.]

289. Moreover, it is important to highlight that Aspen itself, in the official documents sent to the Regulator with reference to the negotiation under exam (cf. *supra*, § 82), expressly stated the uniqueness of each Cosmos drug in their related Class of reference (ATC3).<sup>190</sup>

290. Moreover, the regression analysis suggested by the Party («Dummy Variable Estimator»)<sup>191</sup> – from which it is possible to infer that, following the price increase, the volumes decreased by [30-40]% (cf. *supra*, § 226) – cannot be considered as proof of replaceability with other drugs. This drop in the consumption of Cosmos drugs after the price increases – which however, when calculated on the basis of the volume data provided by AIFA, results more contained than what estimated by Aspen’s economic documentation and in the order of an average 20%<sup>192</sup> – seems more reasonably explained as a plausible reduction of the flows of parallel exportations from Italy due to the alignment of Italian prices to the European average.

291. Lastly, as regards proof, it is particularly relevant that among all the documentation filed – collected during inspections or gathered during the proceedings – and referring to the analyses carried out by the undertaking in view of the price negotiation with AIFA, there is no element indicating that Aspen examined the competitive context of reference of Cosmos drugs. In fact, among said documents there is no trace of an analysis concerning the position of the asserted competitive drugs, nor any evaluations of the kind proposed in the Party’s economic brief, based on the incidence of the therapeutic uses of each drug. No analyses or considerations emerged in which Aspen established the point of balance between the higher profits deriving from the price increase for irreplaceable therapeutic uses and the loss of turnover deriving from the substitution with competing drugs for therapeutic uses for which alternative drugs are present. In this abundant documentation, which highlights the prices requested by Aspen to AIFA, the only reference made is to an international comparison of price as element for defining the “floor price” of the negotiation.<sup>193</sup>

### **VI.3 ASPEN’S DOMINANT POSITION**

292. According to a consolidated community and national orientation, the dominant position consists in a situation of economic power owing to which the undertaking holding it can hinder the persistence of an effective competition on the market in its sector of reference and has the possibility to behave independently from its competitors, customers and, in ultimate analysis, consumers.<sup>194</sup> Basically, when ascertaining a dominant position, what matters is whether the undertaking under exam holds a significant market power.<sup>195</sup>

293. Therefore, the evaluation whether Aspen held a dominant position on the relevant markets identified will be carried out analysing both the absence of actual and potential competition and the possibility to maintain behaviours “considerably” independent from the regulator AIFA.

294. Currently, Aspen does not have to face any real competitors in selling Cosmos drugs in Italy. In fact, Aspen is the only company holding an MA in Italy for the commercialisation of drugs with the active ingredients melphalan, mercaptopurine, chlorambucil and tioguanine.

295. Cosmos drugs are products based on active ingredients whose discovery dates back in time, so much so that they are no longer protected by patent, as of decades, nor are they covered by complementary protection certificates, as confirmed by the Party.<sup>196</sup> Therefore, there are no patent or legal barriers that impede the production of generic versions of these drugs.

296. However, at the moment of the negotiation with AIFA, no ongoing procedures resulted concerning the issuing of MAs for generics of Aspen’s drugs. Therefore, given the technical time necessary to register a generic drug and the lack of MA requests pending for the active ingredients under exam at the moment of the negotiation launched by Aspen, no direct competitive pressure was present.<sup>197</sup>

297. It has been observed that the relevant markets have a contained economic dimension, since Aspen’s drugs treat oncologic-haematological pathologies that have a rather low incidence over the total population, especially when considering the incidence of the so-called solid tumours. Moreover, their main use is limited to maintenance therapies at home, that is a specific phase of the treatment. Consequently, the total turnover of the 4 relevant markets results

---

<sup>190</sup> [Cf. doc. 3 annex 1.]

<sup>191</sup> [Doc. 213, annex 1, p. 14.]

<sup>192</sup> [Doc. 124, annexes 1, 2 and 3.]

<sup>193</sup> [Cf. doc. 3, doc. 3, annex 2, doc. 5, annex A, doc. 12.7, doc. 12.17, doc. 12.27.]

<sup>194</sup> [Cf., for all, Court of Justice, ruling of 13 February 1979, C-85/76, *Hoffmann-La Roche v. Commission*, in *Raccolta 1979*, page 471 and following]

<sup>195</sup> [Cf., *Communication of the Commission concerning the “Orientations on the Commission’s priorities in the implementation of art. 82 of the EC Treaty on the abusive behaviour of dominant undertakings aimed at the exclusion of competitors” (2009/C 45/02).*]

<sup>196</sup> [Cf. doc. 97 and doc. 44.]

<sup>197</sup> [According to the European Commission (*Guidelines on horizontal cooperation agreements*, *Gazzetta Ufficiale C 11* of 14 January 2011): “A company is considered a “potential competitor” of another company if [...] it is likely that, within a short period of time (3), it makes additional investments or bears other conversion costs necessary to enter the relevant market.” As regards the concept of “short period of time,” the Commission “deems that a period not above three years constitutes a “short period of time.”]

to be quite limited, also after the price increase negotiated by Aspen, its last fiscal year closed being around [5-10] million Euros.<sup>198</sup> It is deemed that this element is fundamental for understanding the non-entry of generic drugs in the markets considered, also after the price increase in March 2014. In fact, perspectives of contained sales do not pay back the investment necessary for the entry and make it so that the generic producers' attention is directed toward markets with a more consistent dimension.

298. Therefore, unlike what stated by Aspen in its brief (cf. § 234), the low value of the markets under exam – also valued at the new prices – is an element fit to reduce the incentive for the entry of a generic drug, against the risk not to recover entry costs in a reasonable timeframe.<sup>199</sup>

299. To this regard, the circumstance highlighted by the Party according to which in four Countries worldwide there are generic versions of three out of the four drugs belonging to the Cosmos packages does not appear in contradiction.<sup>200</sup> In fact, they are distinct geographical markets (two out of four outside the EU) with different pharmaceutical regulatory systems, not directly comparable with the Italian market and of which Aspen did not provide data concerning sales volumes and the overall value. Moreover, with specific reference to the potential competitive pressure carried out by the entry of Zydelig (cf. *supra*, note 168), the informative note published by AIFA highlights the adoption of safety measures for the experimentation of the drug, due to the increase in the number of deaths of patients treated with Zydelig (cf. *supra*, § 79).

300. The demand of Cosmos drugs is characterised by a high preference for therapeutic continuity, which derives from the life-saving nature of the products and by the peculiar characteristics that distinguish the drugs under exam. In fact, due to their high tolerability and formulation in tablets, they are particularly fit for therapies targeted to weaker categories of patients (children and the elderly) in the long phases of maintenance therapies at home. These elements make the final demand of Cosmos drugs totally rigid.

301. As mentioned, due to the classification of Cosmos drugs in Class A and H, the MA holder is not free to establish drug prices, but is subject to negotiations with AIFA. The absence of substitutes (true and potential) for Cosmos drugs made the relationship between the undertaking and AIFA inevitably unbalanced to the advantage of the former, as proven by the success of Aspen's negotiation strategy.

302. The relevance for AIFA to preserve the commercialisation of said drugs in Italy, strengthened by the statement of AIFA's CTS concerning the therapeutic irreplaceability of Cosmos drugs and the need to maintain them at the State's expense (cf., *supra*, § 95), as well as the inevitably rigid character of the demand of life-saving anticancer drugs, undoubtedly gave Aspen extreme negotiation power and, consequently, a behaviour of substantial independence with reference to AIFA.

303. A series of practical elements concur toward this conclusion:

- first of all, it is necessary to consider that, in the absence of a negotiation agreement between the parties, the laws in force provide for the drug to be automatically classified in Class C, at a free price (cf., *supra*, § 46). This entails the non-reimbursement by the SSN and the payment at citizens' expense: in case of life-saving drugs this outcome appears inadmissible, as established by the CTS's decision to maintain the drugs in the reimbursement class (cf. §§ 93 and 95);
- secondly, ASPEN's threat during the negotiation to suspend the supply of the drug in Italy's market is of relevance (cf. § 96);
- lastly, the absence of a true negotiation power for AIFA is demonstrated by how the negotiation was actually carried out. In fact, despite AIFA's initial opposition and attempts to contain the first price requests formulated by Aspen, the negotiation concluded with the agreement on price levels absolutely similar to the first proposed by the undertaking (already judged unaffordable for the SSN by AIFA's CPR, cf. § 105).

304. Moreover, the Party's thesis according to which Aspen was allegedly subject to AIFA's countervailing buyer power and obliged to accept a fair price established by the Agency, "*penalty the renunciation to commercialise the drugs in Italy*" (cf. *supra*, § 238), does not respond to reality. Besides, in a counterfactual perspective, it is important to highlight that, had there not been an agreement – as expressly threatened by Aspen (cf. § 96) – the company would not have renounced the turnover deriving from the sales of Cosmos drugs in Italy, because it would have commercialised quantitatives coming from European countries at a higher price (the so-called foreign packs).

305. Therefore, it is possible to conclude that Aspen was not subject to the competitive pressure of other pharmaceutical products, neither real nor potential, on the basis of the following aspects:

- i) the absence of a true competition carried out by authorised generic drugs in commerce;

---

<sup>198</sup> [Cf. doc. 225.]

<sup>199</sup> [According to the estimate of said costs provided by Aspen, the sunk costs that the new entrant would have to bear are equal to 70% of the value of the entire Cosmos market, of which however the new entrant could obtain at the most a share equal to about 20% in value, where the national average market share is applied. The hypothetical entrant would have to bear sunk costs for [1-5] million Euros against a perspective of profits in average corresponding to 1.5 million Euros a year. The sole re-planning of entry costs would take the new entrant more than 3 years, without considering production, distribution, promotion and medical-scientific information costs (since it is a product of new introduction), pharmacovigilance, as well as all administrative costs and of structure that the generic drug company would have to bear in order to commercialise the drugs.]

<sup>200</sup> [Doc. 213, annex 26.]

ii) the rigid demand, given the life-saving nature of the drugs under exam, which determines a strong opposition to change as well as patients' and prescribing doctors' preference for therapeutic continuity;

iii) the absence of a potential competition represented by possible entries of generic drug companies within a reasonable timeframe, due to scarce economic incentives because of the limited dimension of the market of reference. Moreover, it is possible to state that Aspen's market power was in no way mitigated by AIFA's negotiation power during the negotiation for establishing the price of Cosmos drugs.

306. All the above leads to deem that Aspen holds a stable dominant position on the relevant markets identified.

#### **VI.4 ASPEN'S ABUSIVE BEHAVIOUR**

307. Aspen's behaviour, assessed as an abuse of dominant position held on the relevant markets, consisted in fixing unfair prices, pursuant to article 102, letter a), TFUE for products with active ingredients chlorambucil, melphalan, mercaptopurine and tioguanine, in which only Aspen is present with the specialty drugs Leukeran (chlorambucil), Alkeran – injectable and tablets – (melphalan), Purinethol (mercaptopurine) and Tioguanine (tioguanine).

308. Said unfair price fixing was carried out through a negotiation strategy organised by Aspen according to various phases, culminating in the credible threat to suspend the supply on the market of essential drugs for oncological patients, especially elderly people and children (cf. *supra*, section IV.2).

In particular, Aspen carried out the negotiation in an aggressive manner, adopting a strategy based on an insisting negotiation pressure against AIFA, organised as follows:

i) reiteration of the request to pass the drugs into Class C, at patients' total expense, in the awareness of the inadmissibility of said regime for oncological drugs, declared irreplaceable by expert haematologists contacted by AIFA (cf. *supra*, par. IV.2.1);

ii) credible and reiterated threat to suspend the supply of the drugs on the market, had AIFA not accepted the proposals formulated (cf. *supra*, par. IV.2.2);

iii) exploitation of the irreplaceability of the product in the Italian market, through an improper use of the stock allocation mechanism (cf. *supra*, par. IV.2.4).

309. This strategy enabled Aspen to obtain an extremely high price increase – comprised between 300% and 1,500% of the initial prices – corresponding to more than proportional contribution margins, and an extremely important surplus of the new prices compared to the set of costs ascribable to the drugs under exam for the Italian market, also keeping into account a fair remuneration rate of the business activity (cf. §§ 133, 156, 171, 182).

310. The analysis of the prices imposed by Aspen was carried out taking into account the principles of the European jurisprudence, thus assessing the excessive disproportion between production costs and prices applied and ascertaining the imposition of an unfair price also in the light of the specific elements of the case. All this allows to confirm the unfair nature of the prices applied to Cosmos drugs.<sup>201</sup> By implementing the test described (cf. *supra*, par. IV.3), *in primis*, it was possible to calculate the disproportion between the prices applied by Aspen and the costs of the related products, through two different calculation methodologies (analysis of the contribution margin and analysis of the profits and overall costs). Once verified the existence of an extremely relevant gap between prices and costs, the elements of the context were taken into consideration as well as the distinctive characteristics of the case that allow to establish the unfairness of the prices examined.

311. To this regard, it is important to highlight that the fact of qualifying the prices of Cosmos drugs unfair, pursuant to article 102, letter a), TFUE, after the negotiation between Aspen and AIFA, is facilitated by the specific characteristics of the case under exam. In particular, it is hereby highlighted that Cosmos drugs have been in commerce in their current formulation for various decades. Therefore, the typical expenses for research and development, innovation and medical-scientific information generally mentioned by pharmaceutical companies to justify the high prices of drugs (and that usually tend to it make very difficult to apply unfair prices in this sector) result to be widely amortised. It is hereby reminded that said expenses were born by the previous MA holder and not by Aspen, that purchased the Cosmos package in 2009. Moreover, in addition to the lack of investments in research and promotion, Aspen did not make any qualitative improvement to Cosmos products or to the level of their related service.

##### **VI.4.1. Evaluations concerning the unfairness of the prices applied by Aspen**

312. Aspen's application of the new Cosmos drug prices resulted in an increase of the public and private pharmaceutical expenditure for the purchases of said life-saving drugs, corresponding to a more than proportional increase of the company's profits, lacking any economic justification whatsoever. These prices are thus unfair pursuant to article 102, lett. a), TFUE.

313. It is hereby observed, preliminarily, that the elements of profitability highlighted during the proceedings, with regard to the drugs under exam, contradict what stated by Aspen during inspections, with reference to the fact that

---

<sup>201</sup> [Cf. Court of Justice, C-27/76, *United Brands Company and United Brands Continentaal BV against Commission of the European Communities. Banane Chiquita*, ruling of 14 February 1978; OSA, C-351/12, paragraph 88; , C-52/07, *Kanal 5 and TV 4*; C-226/84, *British Leyland v. Commission*; C-26/75, *General Motors v Commission*; C-30/87, *Corinne Bodson against SA Pompes funèbres des régions libérées*; C-323/93, *Crespelle*; Commission, COMP/C-1/36.915 - *DeuCTShe Post AG – Interception of cross-border mail*; Commission, COMP/A.36.568/D3, *Scadlines Sverige AB v. Port of Helsinborg*.]

the price increases of Cosmos drugs were necessary because said products, when purchased from GSK, generated losses or very low margins.<sup>202</sup>

314. These price increases are not due to investments borne by the group in research and development for Cosmos drugs, considering that these were borne by another company in the '50s and '60s and that the related patent has expired. Moreover, no economic commitment is necessary for their promotion (cf. *supra*, § 32) and the production is realised by third party companies, without any immobilisation of resources by Aspen, with production costs that show a decreasing trend over time (cf. *supra*, § 30) on the basis of what identified by the contracts filed.

A) *The disproportion between prices and costs of Cosmos drugs*

315. The analysis of the prices imposed by Aspen started from examining the disproportion between the prices imposed and the value of the products as expressed by production costs.

316. This phase was carried out first of all establishing the disproportion between prices and costs by measuring the gross contribution margin generated by the products object of the proceedings (cf. *supra*, par. IV.3.2). Moreover, the price-cost disproportion was verified also through a second calculation methodology, based on the comparison between profits valued at the new prices and the so-called cost plus, corresponding to a measure of the overall costs referable to each Cosmos drug, inclusive of direct costs of goods sold, of a quota of indirect costs borne by Aspen and of a return on the sales rate equal to 13%, guaranteeing the company's interest to reach its profit aims (cf. *supra*, par. IV.3.3).

317. Both the methodologies applied allowed to reach the conclusion of the existence of a very strong disproportion between the prices imposed by Aspen and the overall costs borne by the same, for a measure definitely higher than the disproportion of prices over costs equal to 25%, already deemed as the expression of an abusive exploitation on the basis of the decisions made at European level for the infringement of article 102, letter a), TFUE (*sub specie* of unfair prices).<sup>203</sup>

318. The first methodology highlighted that in 2013 – thus before the launching of the negotiation under discussion – the drugs under exam produced a contribution margin of the net business outcome totally in line with Aspen's average contribution margin (cf. *supra*, § 151). The contribution margin assured by each Cosmos drug already before the price increase also allowed to recover the indirect fixed costs borne by the undertaking, as evident from the holding's financial statements (cf. *supra*, §§ 154-155). The price increases obtained through the negotiation – corresponding to percentages comprised between 300% and 1,500% – assured an extremely important increase of the contribution margins of Cosmos drugs (cf. § 155).

319. The second methodology adopted highlighted that – for each drug considered – the prices applied in the Italian market assure the group with profits in excess with reference to an all-inclusive measure of all the costs reasonably borne by Aspen for their realisation. These are defined cost plus, also including a percentage of sales remuneration (that is a measure of profitability of the activity carried out), answering the values in average achieved in the pharmaceutical sector by groups active especially in selling generic drugs (13%), such as Aspen.

320. This positive difference between profits and costs assumes extremely high percentage values, comprised between [100-150]% and [350-400]% of the cost plus, despite the analysis was carried out assuming hypotheses strongly favourable for the company (cf. §§ 158-176), among which, in particular: the choice to identify indirect costs to allocate to the Italian market in the APHL holding's financial statements; to allow, in the calculation of the direct costs following raise in prices, an increase of said specific costs in a measure equal to the increase that said item of cost (cost of sales) registered at European level; to apply a sales remuneration rate equal to the average one of the main global pharmaceutical operators commercialising generic drugs.

The conclusions do not change even when considering the costs for purchasing the Cosmos trademarks as direct costs. In fact, also in such hypothesis, the percentages of the excess of profits over the total costs remain extremely high (cf. § 188).<sup>204</sup>

321. The Party contested several of the Offices' assumptions concerning the disproportion analysis (cf. § 248).

322. First of all, Aspen observed that the use of direct costs as allocation key of indirect costs does not seem correct. However, it has already been discussed that choosing sales profits to determine a division coefficient of the indirect costs – suggested by Aspen – is flawed by circularity: sales profits are obviously affected by the prices object of evaluation and their use as allocation key determines the calculation of higher costs due to the high level of prices.

Moreover, it is undisputed that the cost of goods sold represents the best approximation of the inputs used in the realisation of a good. Therefore, it is totally plausible to assume that the indirect costs affect the production of that good in the same proportion of the cost of the goods sold.

---

<sup>202</sup> [Doc. 44, p. 6.]

<sup>203</sup> [Cf. Decision of the EC Commission of 25 July 2001, case No. COMP/C-1/36.915 - DeuCTShe Post AG – Interception of cross-border mail, para. 156, 162, 166 and 167; UK Competition Appeal Tribunal, decision of 7 November 2008, Albion Water Ltd, Albion Water Group Limited v Water Services Regulatory Authority and Dwr Cymru Cyfyngedig, United Utilities Water PLC intervening Case Number 1046/2/4/04 [2008] CAT 31, para. 265. ]

<sup>204</sup> [The percentages of excess over cost plus are collocated in this case in a range comprised between [100-150]% and [300-350]%.]

323. Secondly, Aspen deems that a timeframe of 20 years for the amortisation of the costs borne by the group for purchasing from GSK the rights to commercialise the drugs, is exceedingly long. To this regard, it is important to consider that, in the group's accounting rules, said rights are inserted among the intangible assets amortised by estimating a useful life between zero and forty years.<sup>205</sup>

On the other hand, to allow an amortisation of said costs in a timeframe of only 10 years, as requested by Aspen, would entail that the useful life of the same should end in 2019 (because the related rights were purchased from GSK in 2009). This would mean that the entire process for reviewing prices, as well as all the activities carried out by the group to establish administrative and distribution structures in Europe, were faced with the perspective of exploiting said investments in a timeframe of only 5 years (the European branches were established in 2012-2014 and the price renegotiation occurred in the same years).

324. Therefore, it is hereby reasserted that the assumption of a timeframe of 20 years for the amortisation of the trademarks, starting from when the Cosmos products were purchased, seems reasonable.

325. Moreover, Aspen considers the application of a ROS equal to an average 13% of the generic drugs sector insufficient and asked to be recognised, in calculating the burdensomeness of prices, the sales remuneration rate that it realised on its products, equal to [15-20]%.<sup>206</sup>

This objection is deemed unreasonable since, from a methodological viewpoint, the application of a "third" datum (external the company) appears more correct, as it avoids the risk of evaluations flawed by the conducts object of the exam hereof.

Lastly, Aspen highlighted the non-consideration in the analyses carried out of several items of cost and indirect profits (other operating income, investment income, financing costs). To this regard, it is hereby observed that two out of three of the items mentioned by the Party represent profits and, therefore, their non-consideration in the calculation (decided on the basis of their contained amount) is at the company's advantage; moreover, the item "financial costs" was omitted from the calculation because widely recovered by a sales remuneration equal to 13%.

326. However, to prove the irrelevance of the objections concerning the percentage of ROS applied and the non-consideration of the mentioned items of cost and indirect profits, the disproportion between prices and costs was recalculated on the basis of said assumptions. The percentages of excess of the prices applied by Aspen compared to the costs recalculated are comprised between [100-150]% and [250-300]%.<sup>206</sup>

Therefore, the application of the ROS realised by the Aspen group and the allocation of further items of costs and indirect profits highlighted by the Party, marginally modify the results of the analysis.<sup>207</sup>

327. Although there is no regulatory framework that defines the size that the gap between prices and costs has to have in order to be considered an indication of an abusive conduct, the values observed in the case at hand represent multiples of percentages of excess judged indicative of an abusive conduct in various European precedents.<sup>208</sup> To this regard, it is hereby highlighted that the Party made a methodological mistake in comparing the datum taken as reference by the CRI - that is, 25% of the excess of profits on costs of the case *DeuCTShe Post* - with the data emerging from the various jurisprudential precedents mentioned by the same: the percentages mentioned by Aspen, in fact, refer to price increases and not to the excess of profits on costs. Therefore, they should be compared with the price increases verified in the case at hand. By so doing, also the precedents mentioned by the Party support the Offices' conclusions, when considering that the price increases comprised between 300% and 1,500% of the case under exam are absolutely in line with those identified in the cases recalled by Aspen (+500%, +900%; cf. *supra*, § 250).

328. Lastly, it is hereby reminded that, in both methodologies used for calculating the prices-costs disproportion, the analysis carried out is based on Aspen's internal accounting data. In particular, the documents used in the calculations carried out under par. IV.3.2 B) show an internal profitability analysis (Market P&L) carried out by the Aspen group for each product and for each geographical market. The content of said information was not contested by the Party during the proceedings.

*B) (follows) The unfairness of the prices applied by Aspen*

329. The mentioned disproportion between the price requested and the actual cost borne by Aspen with reference to the drugs under exam is considered lacking of any reasonableness whatsoever and indicative of unfair prices pursuant to article 102, letter a), of TFUE. This conclusion stands on the exam of various contextual and behavioural factors, specific of the case at hand.

---

<sup>205</sup> [In addition, Aspen qualifies Cosmos drug trademarks as indefinite useful life intangible assets which, on the basis of international accounting standards, is the classification reserved to assets for which it is not possible to forecast the remaining useful life depending on several characteristics connected also to the market and the existing competitive pressure and that, therefore, are not object of amortisation.]

<sup>206</sup> [Should the same exam be carried out ascribing the costs for purchasing the trademarks as direct costs, the percentages of excess are comprised between [50-100]% and [200-250].]

<sup>207</sup> [The analysis was carried out according to the methodology described under IV.3.3, substituting the application of the percentage of 13% with [15-20]% and allocating the further items of cost and indirect profit mentioned by Aspen (present in Table n. 4) according to the same allocation keys of the indirect costs ai. ]

<sup>208</sup> [Cf. *supra*, Note No. 203 (*DeuCTShe Post and Albion Water II*).]

### *The intra-temporal comparison of prices*

330. It is necessary to highlight that the price evolution analysis from a temporal viewpoint appears particularly relevant, also in consideration of the impossibility to compare prices of competing drugs, given the irreplaceability with other products authorised to be commercialised in Italy. Another aspect is the insignificance of a comparison with the prices of Cosmos products in other national markets of the European Union, given the differences existing in the healthcare systems and pharmaceutical regulations in the various countries, as well as in consideration of the pan-European price increase strategy.

331. Moreover, the comparison between the new and old prices assumes particular relevance since the original prices were applied without modifications by the previous MA holders, from the very first introduction on the market.

332. To this regard, it was observed that upon the first price determination of an innovative drug of new introduction in commerce, AIFA keeps into consideration the need to remunerate the research activity borne by the company for the realisation of the drug, also with reference to costs for failed experimentations. The initial prices, on the basis of the estimated useful life of a product, are set at a level that makes the investment borne by the company for the discovery and development of the product remunerative. Basically, it is legitimate to assume that, upon the first introduction in commerce of Cosmos drugs, the initial prices allowed to recover said costs and were to guarantee the sole covering of the marginal costs.<sup>209</sup>

333. According to the Party's related objection, the increases under exam are justified since the prices before the negotiation under exam - dating back to the first introduction of Cosmos drugs on the market - would have had to be re-evaluated for inflation. Actually, the proven suitability of the initial prices of Cosmos drugs for covering the marginal costs necessary for their production and commercialisation absorbs the matter concerning the adjustment of the cost of life. In fact, all the costs borne by Aspen for the realisation of said drugs are obviously adjusted to inflation.

334. Moreover, the consideration of the organisational differences between Aspen and GSK, that allegedly justify the different price policies, appears lacking in value, having been proven that said prices resulted already suitable to guarantee a positive marginality for the company (cf. § 151).

335. An indisputable index of the unfairness of the new prices is the actual size of the percentage increases obtained (comprised between 300% and 1,500% of prices already suitable to guarantee a profit margin), which determined a more than proportional increase of the business margins.

336. Said price increases, unlike what stated by Aspen, were not necessary for losses or very low margins generated by said products at the moment of their purchase from the GSK group.<sup>210</sup> In fact, examining the transfer agreement of Cosmos products between GSK and Aspen, collected during inspections, it is clear that, at the moment of the transaction, said product portfolio produced a gross margin of about [1-50] million Euros at global level.<sup>211</sup>

### *The lack of economic justifications for the price increases*

337. The Party did not carry out cost evaluations in defining the negotiation strategy, nor while carrying out the negotiation with AIFA (cf. *supra*, par. IV.2). Contrarily to what stated by Aspen, the existing rules oblige the company, in price negotiations following the first, to document increases in drug production costs: the Guidelines published on AIFA's website are very clear to this regard, specifying that increases in general expenses or common costs not directly ascribable to the specific drug are not admitted as justification for a price increase request.<sup>212</sup> The only motivation for requesting the price increase is the need to align the Italian prices to those in force in other European countries (cf. § 91).

338. The sole general reference to several items of cost borne by Aspen is found in the letter dated 14 October 2013 (cf. *supra*, § 96), which highlights the need to "recover" costs for medical-scientific information, for cost adjustment to GMP qualitative standards,<sup>213</sup> and for the fulfilment of pharmacovigilance obligations.<sup>214</sup> However, no analysis or

---

<sup>209</sup> [To this regard, point 8.11 of the scheme of the dossier annexed to CIPE Resolution expressly provides for the company to indicate the investments carried out in research activities. Cf. *supra*, note 26.]

<sup>210</sup> [Doc. 44, p. 6.]

<sup>211</sup> [The annual average exchange rate in 2008 was equal to 0.796285 €/£. Cf. doc. 20.3.]

<sup>212</sup> [Doc 5. Cf. <http://www.agenziafarmaco.gov.it/it/content/nuovo-sistema-online-la-negoziante-dei-prezzi-e-il-rimborso-dei-farmaci-16012014>.

With reference to negotiation rules, Aspen stated that – due to the dated first introduction on the market of the drugs under exam – the prices of these specialty drugs had never been negotiated with AIFA. In this view, the negotiation opened by Aspen could be intended as a first negotiation. In this hypothesis, however, it is hereby observed that the obligation for the company to submit related documentation as provided for by CIPE Resolution No. 3/2001 with reference to the costs of the specialty drugs is even more forcible than what required by AIFA within the following renegotiations, having to produce all the information of costs provided for by point 8 of the dossier annexed to CIPE Resolution No. 3/2001 (cf. *supra*, § 45).]

<sup>213</sup> [The GMP have their juridical basis in articles 46 and 47 of Directive 2001/83/EC, ("Community code for human-use drugs") and define the requirements that have to be satisfied during the development, production and control phases of drugs. In 1989 the European Commission issued Guidelines on Good Manufacturing Practices - Medicinal Products for Human and Veterinary Use, followed by various updates over the years. More forcible requirements are provided for the production of several drug categories, among which sterile medicines: annex 1 to the mentioned Guidelines, "Manufacture of Sterile Medicinal Products" in force as of September 2003 and last updated in 2009.]

datum supporting said general references was found in the documentation acquired during inspections, nor produced by the Party.<sup>215</sup>

339. On the other hand, it has been proven that there are no reasons for considering the increases of said items of cost at Aspen's expense. In fact, no investment in the medical-scientific promotion is necessary for the drugs under exam, already affirmed on the market as of decades, widely experimented and renown to the scientific community.<sup>216</sup> As regards the costs for pharmacovigilance and costs for the adjustment to GMP's productive standards, it is hereby specified that said costs involve the entire pharmaceutical production and not specifically Aspen's drugs (and, therefore, not admitted by AIFA as a justification for price increases, cf. § 48). Moreover, Aspen does not produce Cosmos drugs, but purchases them from third party producers and, therefore, the costs concerning compliance with the GMP standards rest on the producers and are reflected in the purchase prices of the drugs paid by Aspen (that, as mentioned, show a decreasing trend over time. Cf. § 30).<sup>217</sup>

340. Nonetheless, as a guarantee for the Party, the disproportion of the new prices was established over a total cost also keeping into account an increase in direct and indirect costs in a measure equal to what registered in the financial statements of the South African holding between the last fiscal year preceding the application of the new prices and the following fiscal year 2014-2015 (cf. Table n. 10). As mentioned, this analysis proved that the new prices exceed costs in an extremely relevant measure (comprised between [100-150]% and [350-400]%).

341. During the proceedings, Aspen highlighted the need to recover the costs for investments borne when purchasing the portfolio of Cosmos products from GSK. As mentioned (*supra*, § 179), Aspen stated that the transaction under exam had a total cost of about [300-400] million American dollars for the entire Cosmos package, without being able to provide a division of said amount per country. Also taking into consideration the direct recover of said investments, the results of the test on the disproportion do not change the conclusions with reference to the excess between prices and costs. In fact, the percentages in excess of the profits over total costs remain at an extremely high value (comprised between [100-150]% and [300-350]%).

342. On the other hand, the unreasonableness of the price levels imposed is proven by the extremely high profitability rates that Aspen obtained from the investment in purchasing the Cosmos trademarks for the Italian market, comprised between [20-30]% and [30-40]% (cf. *supra*, § 191).<sup>218</sup> If the same fiscal year was closed under the hypotheses of a ROS equal to that actually realised by Aspen and including the other items of cost and indirect profits (as requested by the Party), the internal profitability rate of Cosmos drugs is around [10-20]% and [30-40]%.<sup>219</sup> It is clear that the application of the new prices under exam assured Aspen with profitability percentages for each product line significantly higher than the average cost over the capital invested observed in the pharmaceutical sector, equal to about 8% (cf. *supra*, § 192).<sup>220</sup>

343. In conclusion, with reference to the absence of realistic economic justifications for the price requests formulated, Aspen's statement appears relevant as it admits, in mentioning the position of AIFA's Head of the UPR with reference to the way the negotiation was carried out, not to have provided any relevant reason to justify the prices requested: "[...] (as we didn't mention any strong base other than the prices in UE, for asking an increase of prices) [...]" [emphasis added].<sup>221</sup>

#### *The lack of extra-economic benefits for patients*

344. The investigation proved the lack of extra-economic benefits for patients and the SSN. In fact, it was observed that the price increases registered did not correspond to any qualitative improvements in the products or related services. Cosmos drugs were developed many years ago by a different pharmaceutical group and have remained unvaried in their composition and formulation. With reference to the service, no advantage for patients or for the SSN followed the price increase. On the contrary, at distribution level, Aspen's choices concerning the allocation of the quantitative of product in the price negotiation with AIFA contributed in worsening the issue related to the lack of drugs identified in Italy (cf. *infra*, §§ 373-377).

---

<sup>214</sup> [With reference to costs deriving from pharmacovigilance rules, these are general provisions applicable to the entire pharmaceutical industry, aimed at monitoring the safety and quality of drugs introduced on the market. At European level, the EMA (European Medicine Agency) defined the guidelines on pharmacovigilance best practices ([http://ec.europa.eu/health/human-use/pharmacovigilance/index\\_en.htm#geninf](http://ec.europa.eu/health/human-use/pharmacovigilance/index_en.htm#geninf), last accessed on 2 September 2016).]

<sup>215</sup> [Cf. doc. 5, annex A.]

<sup>216</sup> [To this regard, the statements of GIMEMA's specialists and what emerged from the documentation collected at GSK during inspections (cf. § 30 and § 74, note 58). ]

<sup>217</sup> [Cf. doc. 116, annex 1 (pages 5 and 6) and 2. The contracts produced by the Party show a decreasing trend of the purchase prices paid by Aspen for the realisation of the drugs under exam.]

<sup>218</sup> [Even when considering the sole margin deriving from the excess of profits compared to costs (net of the margin corresponding to a ROS of 13%) the profit rate of the return on capital invested is stabilised at extremely high values, between [10-20]% and [30-40]%.]

<sup>219</sup> [As mentioned above, considering the sole excess on costs, the return percentages range between [10-20]% and [30-40]%.]

<sup>220</sup> [Purinethol, [30-40]%; Alkeran, [30-40]%; Leukeran, [20-30]%; Tioguanine, [10-20]%.]

<sup>221</sup> [Cf. doc. 12.25.]

345. Basically, the economic value of the service provided is correctly measured by the overall direct and indirect costs identified in the previous sections, without it being possible to consider other factors not reflected by costs increasing said value.

346. To this regard, the Party's considerations concerning the various non-strictly economic factors that can affect consumers' willingness to pay, these are inadmissible in the case of life-saving products: it is clear that the application of the concept of willingness to pay to oncologic pharmaceutical products lacking therapeutic substitutes would make any price increase plausible, failing the admissibility of exceedingly expensive prices, whatever the level of prices imposed. In this view, the Party's comparison with common consumption goods, such as *[omissis]*, does not seem appropriate.

#### *Nature of Cosmos drugs and characteristics of the Aspen group*

347. A further fundamental factor in evaluating the unfairness of the prices imposed by Aspen is represented by the nature of the drugs, used in the treatment of severe oncologic pathologies affecting sub-populations of particularly weak patients, that do not have therapeutic substitutes in particular phases of their disease. The lack of replaceable products at therapeutic level and the preference of doctors and patients for therapeutic continuity, due to the anticancer nature of Cosmos drugs, establish a strong rigidity of the demand toward said life-saving products, with the consequence that the SSN (and even patients, for the percentage of purchases carried out with "white prescription") totally bears the price increase imposed by Aspen due to its dominance (cf. §§ 303 and 304).

348. Moreover, the opinion concerning the unfairness of prices applied by Aspen cannot disregard the consideration of Aspen's mission and the strategy carried out for purchasing the product portfolio under exam also in other European countries. As mentioned, Aspen is a pharmaceutical group mainly active in the distribution of generic drugs, as well as trademark drugs developed by other companies. Research and development activities do not characterise the group (cf. § 195). With reference to the products object of these proceedings, with a patent expired decades ago, Aspen does not invest in research and development, nor medical-scientific promotion, as expressly stated by Aspen itself. This circumstance excludes the possibility to consider the application of a pricing aimed at recovering possible investments (for the development of the same or other products).

349. The purchasing of the anticancer package under exam (with an expired patent, but characterised by the lack of replaceability which gives to the MA holder absolute market power) and the following redefinition of price increases in the various European countries – considered in their whole – corresponds to a business model that exploits market niches to impose prices totally lacking a reasonable relationship with the costs borne or the service provided to consumers and lacking any investment whatsoever socially useful aimed at innovation. This particularly aggressive strategy does not seem to be an isolated phenomenon (cf. § 129).

#### *Damage for the SSN*

350. Lastly, the data provided by AIFA indicate that, due to the price increases under exam, the total healthcare expenditure for the drugs considered passed from 1.5 million Euros in 2013 to about 6.4 million Euros in 2014,<sup>222</sup> year in which the price increases had an impact for only eight months (since the new prices were decided at the end of March 2014 and became effective from May 2014).<sup>223</sup> Basically, the SSN and patients currently bear an expense for Aspen's drugs about five times higher than what borne before the price increases discussed herein, corresponding to a percentage increase of the healthcare expenditure equal to about 500%.<sup>224</sup>

351. Therefore, the extremely high prices obtained by Aspen compared to the economic value of Cosmos drugs caused a direct effect on the SSN's resources. To this regard, it is important to highlight that the public resources destined to the pharmaceutical expenditure are limited and determined by the State budget. The dispersion of public funds caused by Aspen's abusive behaviour – with the higher expense born by the SSN for purchasing said drugs – inevitably entailed the reduction of funds available for other purposes falling within public healthcare policies.

#### **VI.4.2. The negotiation with AIFA: instrumental exercise of the right to renegotiate prices with the aim to obtain unfair prices**

352. The unfair prices, as defined by the analysis carried out above, were obtained through an illicit pressure carried out by Aspen during its negotiation with AIFA. Therefore, the undertaking's negotiation strategy represented the tool for imposing on the SSN and on patients unfair prices for its anticancer drugs, constituting at the same time the cause and demonstration that AIFA lacked negotiation power over Aspen.

353. The negotiation with AIFA was characterised by Aspen's insistence on the need to conclude the negotiation quickly, this being the basis for the entire negotiation *iter*. The group repeatedly asked AIFA to provide a quick decision, complaining over and over again, also in formal documents, about the lengthiness of the negotiation and

---

<sup>222</sup> [Cf. doc. 124, annex 1, annex 2.]

<sup>223</sup> [Cf. doc. 12.29.]

<sup>224</sup> [Aspen's objection concerning the percentage incidence of the increase of the public healthcare expenditure (supra, § 257) is clearly wrong. In fact, considering that the 7 million Euros of the public healthcare expenditure concern only 8 months of 2014, the projection of the increase of the healthcare expenditure registered in 2014 on 12 months produces an annual expenditure equal to about 8.9 million Euros, equivalent to an annual variation of about 500% of the expenditure borne before the price increases. ]

placing said argument as the basis for its threat to suspend the direct supply of the drugs under exam in the Italian market.<sup>225</sup>

A) *The reiteration of the request to pass in Class C and the threat to suspend the supply of the drugs*

354. In April 2013 Aspen opened the negotiation under exam requesting the reclassification in Class C of the drugs considered herein, in the full awareness of their irreplaceability and, therefore, of the inadmissibility of said request (cf. *supra*, §§ 91 and following), using as sole argument the need to align the prices of Cosmos drugs with the higher prices in force in other EU countries.<sup>226</sup> This request, reiterated in the negotiation, is considered instrumental.

355. To this regard, no relevance is given to the Party's arguments concerning the ambiguity that allegedly characterised the regulatory framework in force in April 2013, due to the entering into force of Decreto Balduzzi and its introduction of the so-called non-negotiated Class C and the obligation for AIFA to carry out an Extraordinary Review of the Drug Code within December 2015 (cf. *supra*, par. III.3).

356. In fact, it is hereby observed that the non-negotiated Class C is a classification introduced expressly for drugs at their first introduction on the market and lacking classification for reimbursement purposes. In no way Decreto Balduzzi can be considered applicable to Aspen's drugs, authorised on the market decades ago and in Class (A or H) for just as many years.<sup>227</sup> Analogously, as regards the reference to the presence of Cosmos drugs in the list of drugs to be evaluated within the review of the Drug Code (delisting) in the attempt to legitimise the reclassification request in Class C, it must be highlighted that the documentation produced by Aspen indicates that the company acquired awareness of said review procedure reading the notice published on AIFA's website in July 2013, that is several months after submitting the request to pass in Class C (cf. *supra*, §§ 52 and following).

357. In conclusion, no element of juridical uncertainty characterised the regulatory framework in force at the time of Aspen's first request to reclassify the drugs at patients' expense. The sole element of which the company was aware in 2013 was the appointment entrusted to AIFA by Decreto Balduzzi to review the Drug Code within December 2015.<sup>228</sup>

358. The fact of opening the negotiation with the request to pass in the Class at patients' expense was part of Aspen's negotiation strategy, as proven by the mentioned internal exchange of e-mails (cf. §§ 98-99).<sup>229</sup> In fact, AIFA stated that opening the negotiation with Aspen's request to pass its drugs into Class C "represented a totally exceptional circumstance: [...] the first case in which this has ever occurred for anticancer drugs, given their life-saving nature and irreplaceability certified by expert haematologists ..." and "[...] it undoubtedly represents an aggressive behaviour carried out by the company within the negotiation with AIFA" (cf. *supra*, § 92). This evaluation of exceptionality – that the Party deems insignificant – is the authoritative opinion of the Regulator of the sector, based on its experience deriving from negotiations carried out for all specialty drugs under marketing authorisation in Italy.

359. Following the CTS's negative opinion concerning the admissibility to pass into Class C and the consequent transformation of the procedure into a price renegotiation, upon AIFA's request Aspen formulated a first proposal with letter dated 14 October 2013. The prices presented, not far from those approved as result of the negotiation, corresponded to extremely high price increases (comprised between 300% and 1,500% of the initial prices).

The letter is absolutely clear concerning the threat to suspend the direct commercialisation of the drugs considered on the Italian market had the parties not reached an agreement (cf. *supra*, § 96).<sup>230</sup>

360. Moreover, Aspen associated the threat to withdraw the drugs to the reiterated request to classify the same in Class C, although fully aware of the impossibility for AIFA to accept said request due to:

- the CTS's clear statement expressed on 10 September 2013 on the basis of the opinion given by the haematologists in July 2013;

- the answer received on 2 October 2013 from AIFA's Board Secretary concerning the CTS's decision not to proceed with the delisting of the drugs under exam, within the scope of the review of the Drug Code.<sup>231</sup>

361. The minutes of the CTS's following meeting held on 6-8 November 2013 – during which Aspen's price proposal was examined – highlight the undertaking's position and related threat: "[...] Should AIFA not publish in the Official

---

<sup>225</sup> [By way of example, cf. doc. 5, annex A (*supra*, § 96): "[...]Aspen's priority is to reach a significant and quick price increase of the sales price in force, nonetheless hoping to maintain the reimbursement class currently held [...] However, the negotiation lasted more than hoped ... this Office be able to proceed and quickly conclude (November 2013) this reimbursement negotiation [...]" [emphasis added].]

<sup>226</sup> [Cf. doc. 3, annex. 1.]

<sup>227</sup> [Moreover, Aspen's requests never referred to the non-negotiated Class C.]

<sup>228</sup> [To this regard, it is important to consider that many of the drugs in the list organised by AIFA to this end were not excluded from the Drug Code after the evaluation carried out by AIFA's bodies. This confirms that, as in every evaluation process, the composition of the list represented only the first step of the assessment procedure.]

<sup>229</sup> [In order to prove Aspen's awareness, relevance is given to the e-mail in which Mr. F, referring to the minutes of the CTS of 10-11 September 2013, stated the validity of Aspen's strategy (cf. *supra*, § 98), thus qualifying the choice to submit a request for Class C as a precise strategic choice and not, as stated by Aspen in its brief, a "mere contact" with AIFA.]

<sup>230</sup> [Cf doc. 5, annex A.]

<sup>231</sup> ["[...] with reference to the list of drugs you sent us, those object of the CTS's review were as follows: Purinethol (mercaptapurine), Myleran (busulfan), Leukeran (chlorambucil), for which the Committee deemed that there were no grounds for their delisting in the non-reimbursement Class." (Class C, editor's note).]

Gazette the decision to reclassify in Class C or re-establish the price in the reimbursement class, ASPEN communicates that it will suspend the commercialisation of the specialty drugs falling within the request as of January 2014" [emphasis added].

362. The exchange of e-mails dated November and December 2013 clearly indicate that i) the strategy pursued by Aspen was aimed at putting AIFA under pressure, threatening to withdraw the drugs and reiterating the request to pass them into Class C and ii) that such strategy was organised by Aspen's top management (Mr. B of APHL), contrarily to the Party's thesis according to which the external consultant – however commissioned by Aspen–qualified said choice as a negotiation strategy.

363. In particular, the e-mail dated 5 December 2013, sent from Mr. B (the holding's marketing manager) to Mr. E, highlights that, Mr. B indicated the strategy to adopt had the minimum price acceptable - corresponding to the French price – not been reached. Said strategy consisted in insisting on the reclassification in Class C so as to have the possibility to freely fix prices: "If this can't be agreed then push hard to get C class on all products so we have free pricing."<sup>232</sup> Mr. B's second e-mail dated 10 December 2013 results to be along the same line. In fact, it indicates that, lacking an agreement with AIFA on the prices proposed or the passing in Class C (the so-called *delisting* procedure), the company would have suspended the supply of the drugs on the market: "Should AIFA not agree to pricing in this range we should then obtain approval to delist the remainder of the products from reimbursement per our initial request to avoid a January exit from the market[.] Should this not be achievable we would initiate the January exit and suspend supply if/until the pricing can be resolved [emphasis added]."<sup>233</sup>

364. The request to pass to Class C was reiterated by Aspen in the meeting held on 16 December 2013 between the CPR and the undertaking, during which an actual negotiation took place between the two (cf. § 105). In fact, the minutes highlight that the CPR judged Aspen's proposal unaffordable and in turn proposed prices aligned with the lower prices registered in other European countries. Aspen's representatives, after contacting the Parent Company by phone, reiterated the proposal of reclassification in Class C, proving the pressure placed on AIFA. The CPR reasserted the oncologists' opinion concerning the essentiality of said drugs and once again stated that the request was unacceptable, suspending the procedure and asking the company to formulate a second price proposal based on actual prices applied in Europe to the various healthcare systems.<sup>234</sup>

365. The analysis carried out indicates that Aspen's threat to suspend the supply would have worsened both the Italian patients' situation – with reference to the difficulty to find the drugs – and the SSN's, in terms of higher costs for purchasing the products (cf. *supra*, § 63). In fact, had the threat been put into practice, the supply for Italian patients would have taken place through import authorisation requests submitted singularly and spontaneously by the different healthcare structures – and not by the MA holder – once noticed the lasting absence of the product on the market.

366. On the matter, Aspen stated that the company would have activated the procedure provided for by D.M. of 11 May 2001 "at due time," without better clarifying the meaning of said statement. In any case, the letter of 14 October 2013 (as well as the documents collected during inspections that refer to the hypothesis of a suspension of the supply) does not refer in any way whatsoever to the procedures provided for by the mentioned D.M.. On the contrary, it indicates the hypothesis to supply "foreign packs" at the prices applied abroad, unlike what provided for by the Decree, which allows the payment of the price authorised in Italy and not abroad.

367. AIFA explained with clarity the cases in which the supply from abroad is admitted by the laws in force: the hypotheses of authorisation regulated by D.M. of 11 May 2001 are not compatible with what prospected by the undertaking. In fact, the causes that justify a request to import from abroad pursuant to said decree have an exceptional nature and very different from the decision to suspend the supply of a drug (cf. par. III.5.2).<sup>235</sup> Any other form of extraordinary import from abroad allowed by the laws in force however entail the payment of the price applied in the foreign country of provenance.

368. The only exception would be represented by the case of the so-called Named Patient Based Programmes, that is programmes (regulated by D.M. of 8 May 2003) implementable in absolutely particular conditions, related to the opportunity to guarantee patients affected by severe or rare pathologies, lacking any therapeutic substitutes, the use of a drug not authorised in their own Country because still under experimentation (the so-called "compassionate use"). Therefore, it is clear that the decision to suspend the supply of a drug for reasons linked to the protection of the

---

<sup>232</sup> [Doc. 12.7 (*supra*, § 103).]

<sup>233</sup> [Cf. doc. 12.8 (*supra*, § 104).]

<sup>234</sup> [The reasons for such request from the CPR are explained clearly by Mr. F in the e-mail sent to Mr. B on 19 December 2013: basically, AIFA requested to anchor the new prices to an average of the actual prices, net of the discounts applied to the healthcare systems, having identified a positive difference between the ex factory prices in force in the various countries (net of discounts by law) and the actual prices (calculated on the basis of the data concerning turnover and volumes initially provided by the company). Mr. F explained that this need is given by the lack of any justifications whatsoever ordinarily admitted in price renegotiation (cf. *supra*, § 106).]

<sup>235</sup> [Aspen highlighted that AIFA indicated the pending of regulatory procedures among the justifications that the company can adduce for communicating a state of temporary shortage of a drug, according to the D.M. under exam. It is evident that the hypothesis mentioned by AIFA refers to regulatory procedures that can determine a state of temporary impossibility for the producer to guarantee the adequate supply of a drug and not certainly a price renegotiation procedure of a specialty drug already on the market. ]

undertaking's commercial interests can in no way whatsoever be assimilated to the cases regulated by D.M. of 8 May 2003.

369. In conclusion, had the suspension of the drug supply threatened by Aspen been carried out, the oncologic drugs object of the investigation would have been available for Italian patients:

- i) only against an import authorisation request submitted by the single healthcare structures;
- ii) only at hospital pharmacies of the healthcare structure that submitted the import authorisation request and not at territorial pharmacies;
- iii) with a non-assessable timeframe, reasonably above the 12 hours imposed by law on the pharmaceutical distributor of drugs regularly commercialised in Italy;<sup>236</sup>
- iv) with an evident lack of territorial homogeneity.

370. With reference to the SSN, the mentioned suspension of the supply would have entailed:

- a) the drug purchase order submitted by the single healthcare structure directly to the MA holder;
- b) the payment of the price in force abroad applied each time by the MA holder on the basis of the country of provenance;
- c) shipment and logistic charges at the expense of the healthcare structure ordering the drugs.

371. Basically, the suspension of the supply of Cosmos drugs, indeed functional in Aspen's negotiation pressure, would have entailed higher costs and relevant inconvenience both for Italian patients and the SSN.

372. On the basis of what observed under §§ 96-106, Aspen's threat to suspend the direct supply of Cosmos drugs was therefore fully credible.

To strengthen the feasibility of said threat, the filed documents mentioned under §§ 123-126 indicate that the group truly suspended the direct supply of the drugs in Spain, lacking an agreement on the price increase, and the drugs were made available to Spanish patients through the supply of "foreign packs," at the prices in force in the countries of exportation.<sup>237</sup>

#### *B) Lack of the products in the Italian distribution network*

373. From the elements acquired it is clear that, during the negotiation with AIFA, Aspen even used the scarce availability of drugs in the Italian distribution network, in various areas and in different moments, as argument to support its price increase request, a factor which affected the conclusion of the negotiation.

374. The filed evidence highlights that Aspen, through the allocation system of the quantities managed at European level, was able to affect the episodes of product shortage within the distribution network, exploiting this aspect to influence the negotiation. The considerations of the wholesaler Mr. L (cf. *supra*, § 113) and Mr. E's statements in the e-mail dated 17 January 2014 (therefore, in full negotiation with AIFA) clearly highlight that the quotas of the product (Alkeran) destined to the Italian market were significantly below the average sales of the previous months, with the consequence of being able to cause the unavailability of the product: "[...] *I have to underline that the allocation quotas for Alkeran Vials and Tablets is significantly below the average sales of the last 8 months. I think that this could have an impact on products availability and performance and should AIFA get to know this info, they could be able to use it to their advantage.*" (cf. *supra*, § 118).

375. This is even more relevant when considering that the shortage of drugs cannot be justified on the basis of production reasons, as stated by the Party in its brief. To this regard, it is hereby observed that the company was able to easily accept AIFA's request - in the meeting held on 22 January 2014 - to increase the production destined to the Italian market by 10% (cf. § 120). If this were not enough, the documents filed prove that Aspen was even ready to consider the destruction of the amounts of product, should this have been functional for reaching its negotiation purposes, as clearly evident in the exchange of e-mails collected, referring to the negotiation with the Spanish regulator (cf. *supra*, § 124).

376. Lastly, the documents filed confirm that the quantities destined to Italy up to the moment in which the new prices were decided were below demand.<sup>238</sup> Basically, Aspen allegedly fixed a quota for the Italian market by managing the stock allocation system of its oncologic drugs in the period prior the price increases.

In fact, said internal exchange of e-mails highlights that there was no longer the need to control the quantities to send to the Italian market at the end of the negotiation: "*I am very happy to announce the publication in the Official Journal of the new prices for all the Cosmos products [...] before scratching out the allocation system for this product, I would like to evaluate sales trend at least for one month [...] Please be prepared for a possible shipment quotas increase.*" [emphasis added].<sup>239</sup>

---

<sup>236</sup> [Cf. doc. 112, pages 8 and 9.]

<sup>237</sup> [Cf. doc. 20.6: "we currently supply Spain with foreign packs for the oncological range due to low prices in Spain" (a) "The plan is that from 1st January 2015 we will continue to sell only 'foreign packs' but at the French price level, i.e. lowest in EU. This will be subject to AGEMED [editor's note, the Spanish pharmaceutical regulatory authority] accepting [...] if [...] they reject the FR price we will cease supply [...] assuming there is no issue, we will supply."]

<sup>238</sup> [Cf. doc. 12.35 B.33.]

<sup>239</sup> [Cf. doc. 12.35 B.33.]

And that there was no longer the need to maintain the allocation system of the quantities for the Italian market having reached the alignment with the European prices: ["... consider that in Italy there is no need for stock allocation anymore. [...] price for Cosmos portfolio is aligned with the other EU countries..."].<sup>240</sup>

377. Therefore, it is deemed that Aspen exploited the temporary lack of Cosmos products in the Italian distribution network, controlling said lack by managing the stock allocation system of oncologic products, using it as a further lever to force AIFA's decision.

#### **VI.4.3. Conclusions on Aspen's conduct**

378. In the light of the above, it is possible to conclude that Aspen infringed article 102, letter a), of TFUE, exploiting its dominant position in the relevant markets by imposing unfair prices – through the instrumental use of the negotiation phase with AIFA – for the specialty drugs Leukeran 2 mg – 25 tablets (chlorambucil), Alkeran 50 mg/10 mg powder and solvent for injectable solution – 1 vial (melphalan), Alkeran 2 mg – 25 tablets (melphalan), Purinethol 50 mg – 25 tablets (mercaptopurine), Tioguanine 40 mg – 25 tablets (tioguanine), with significant prejudicial effects on the SSN and consumers.

379. In order to quantify the abusive conduct it is hereby highlighted that, against price increases ranging between 300% and 1500%, Aspen realised profits in excess over the cost plus as defined above, comprised between [100-150]% and [250-300]%, also recognising a ROS at [15-20]% equal to the group's average ROS. Even ascribing to direct costs the costs borne by Aspen for purchasing trademarks, the percentages of excess remain nonetheless extremely high and comprised between [50-100]% and [200-250]%.

#### **VII. THE PREJUDICE TO INTRA-COMMUNITY COMMERCE**

380. The prejudice to intra-community commerce constitutes one of the conditions for the implementation of article 102 of TFUE. Prejudice to commerce among Member States depends, more specifically, on a series of factors that, among other things, include the nature of the products or services and the position of the undertakings involved.<sup>241</sup>

381. This being said, the abuse in object involved drugs distributed in whole territory of the Italian Republic, thus corresponding to a significant part of the European market. Therefore, the abuse carried out by Aspen is capable for its nature, to hinder the economic integration pursued by the European Union's laws. Hence, this abuse is to be considered capable of prejudicing commerce among Member States. The conducts ascribable to the Party are relevant pursuant to article 102 TFUE.

382. Therefore, on the basis of the above, the behaviour described, being capable of altering commerce among Member States, constitutes an abuse of dominant position, pursuant to article 102 of TFUE.

#### **VIII. SERIOUSNESS AND DURATION OF THE INFRINGEMENTS**

383. Pursuant to article 15, paragraph 1, of Law No. 287/90, in cases of serious infringements with reference to abuse of dominant position or anti-competitive agreements, and keeping into account the seriousness and duration of the infringement, the Authority can order the imposition of a fine. Said fine can amount up to 10% of the turnover realised by each undertaking or body responsible for the infringement in the last fiscal year closed before the notification of the warning, issued upon the outcome of the investigation.

384. According to what expressly clarified by the Court of Justice, "*in order to evaluate the seriousness of an infringement, it is necessary to keep into account a large amount of factors whose character and relevance vary depending on the type of infringement and the particular circumstances of the same.*"<sup>242</sup>

385. To this regard, it is hereby highlighted that the behaviour adopted by the multinational group Aspen integrates an exploitation abuse, as established by the community and national antitrust law. Therefore, it results capable of causing a significant prejudice to the SSN, in terms of higher expenses borne in order to supply drugs to citizens.

386. It is hereby highlighted that the mentioned imposition of unfair prices – for life-saving anticancer drugs, irreplaceable for the weaker segments of the population (the elderly and children) – was realised through an aggressive negotiation, that reached the apex in the credible threat to suspend the direct supply of drugs on the Italian market. The realisation of such threat would have entailed higher costs for the SSN and relevant inconveniences for Italian patients to access treatments (cf. §§ 365, 369, 370 and 371).

387. On the basis of the above, in compliance with the community and national jurisprudential orientations, it is clear that Aspen's imposition of unfair prices constitutes a very serious infringement of competition protection regulations.

---

<sup>240</sup> [Cf. doc. 12.35 B.22.]

<sup>241</sup> [Cf. Court of Justice EU, ruling 11 July 2005, C-42/84, Remia BV and others v. Commission; Communication of the EU Commission on the concept of prejudice to commerce among Member States as mentioned under articles 81 and 82 of EC Treaty (2004/C 101/07, in GUCE C 101/81 of 27 April 2004).]

<sup>242</sup> [Cf., inter alia, EU Court of Justice, C-100/8 to 103/80 (joint actions), Ruling of 7 June 1983, Musique Diffusion Française, para. 120.]

388. As regards the duration of the abuse charged, the outcomes of the investigation proved that the abusive behaviours began at least the moment in which the abusive strategy was started, that is 13 April 2013, date on which the negotiation with AIFA was opened, and still continue to date, since the new unfair prices are still in force.

## IX. DETERMINATION OF THE SANCTION

389. Once ascertained the seriousness and duration of the infringement carried out by Aspen, in order to quantify the sanction to be imposed, it is necessary to keep into account what provided for by article 11 of Law No. 689/1981, as recalled by article 31 of Law No. 287/90, as well as the interpretation criteria provided in the "*Guidelines on the modalities for implementing criteria as regards the quantification of pecuniary administrative sanctions imposed by the Authority implementing article 15, paragraph 1, of Law No. 287/90*" (hereafter, Guidelines), pursuant to the Authority's resolution of 22 October 2014.

390. In the light of point 7 and following of the Guidelines, the basic amount of the sanction is obtained by multiplying a percentage of the sales value - established on the basis of the level of seriousness of the infringement - by the duration of the involvement of each undertaking in the infringement.

391. In particular, the value of reference is that of the sales of services provided by the undertakings involved, that is the turnover deriving from selling Leukeran (2 mg - 25 tablets), Alkeran (50 mg/10 mg powder and solvent per injectable solution - 1 vial), Alkeran (2 mg - 25 tablets), Purinethol (50 mg - 25 tablets), Tioguanine (40 mg - 25 tablets), in the last fiscal year corresponding to an entire year of involvement in the infringement (that is, from 1<sup>st</sup> July 2015 to 30 June 2016), net of VAT and other taxes. To this regard, it is hereby specified that reference is made to Aspen's sales to LFM - that is, the sole distributor of Aspen's products in Italy - not identifying how much LFM sold in that specific year, because of the buy and sell model adopted by Aspen (cf. *supra*, § 29) and the latter not having a direct turnover in Italy.<sup>243</sup> The turnovers of Aspen's sales for said drugs, net of VAT, of other taxes and commission recognised to LFM, <sup>244</sup> are equal to [5-10 million] Euros, on the basis of the last fiscal year closed at 30 June 2016 (from 1<sup>st</sup> July 2015 to 30 June 2016).

392. In order to determine the basic amount of the sanction, a specific percentage is applied to the sales value as established above, identified on the basis of the seriousness of the infringement. According to the Guidelines, the proportion considered is to be set at a level that can reach 30% of the sales value, "*depending on the seriousness of the infringement*" (point 11).

393. According to consolidated community and national jurisprudence, to evaluate the level of seriousness of an infringement it is necessary to keep into account various factors whose character and relevance vary depending on the type of infringement and its particular circumstances. Among these, particular relevance is given to the nature of the restriction of the competition as well as the role and representativeness on the market of the undertakings involved.<sup>245</sup>

394. Pursuant to point 14 of the Guidelines, for the case at hand, relevance is given to the nature of the products object of the investigation - life-saving anticancer drugs - and the level of concentration of the relevant markets, with the sole presence of Aspen.

395. Therefore, the percentage of the basic amount for establishing the sanction is around [10-15]% of the sales value, since the conduct of which the Party is charged is aimed at exploiting Aspen's market power in selling life-saving anticancer drugs, destined to patients affected by severe oncologic-haematological diseases. Aspen exploited its dominant position to obtain extremely high price increases of said drugs, that even reached 1,500% of the initial price, with clear damage for the SSN's economic budget in its whole and for patients. The result is an amount equal to [1,000,000-1,500,000] Euros.

396. The amount obtained is to be then multiplied by the number of years of involvement in the infringement, keeping into account the criteria defined in paragraph 16 of the Guidelines, in which it is established that "*for infringements of one year, the duration shall be calculated on the basis of the actual months and days of involvement in the infringement.*" In the case at hand, the duration of the infringement is equal to 3 (three) years, 5 (five) months and 16 (sixteen) days, considering the beginning on 13 April 2013. Therefore, the basic amount was calculated using "3.45" as multiplying factor, resulting in an amount equal to [3,000.000-4,000.000] Euros.

397. Implementing point 17 of the Guidelines, in order to give to the Authority's sanction power the character of actual deterrence and in consideration of the relevant seriousness of the competition restriction carried out by the Aspen group, it is deemed appropriate to add to the basic amount, a supplementary amount (the so-called entry fee), in the measure of [15-20]% of the value of the sales of goods and services object of the infringement, that is an amount equal to [1,000.000-1,500,000] Euros.

398. In its brief, Aspen asked for the implementation of one or more extenuating circumstances on the basis of the following reasons: *i*) it collaborated during the proceedings and, in particular, it allowed the participation at the hearing

---

<sup>243</sup> [Doc. 125.]

<sup>244</sup> [Doc. 194 and doc. 225.]

<sup>245</sup> [Cf., by way of example, Council of State, ruling No. 896 of 9 February 2011, and No. 5171 and No. 5172 of 16 September 2011, with reference to the case I694 - Pasta price list.]

held on 7 May 2015 of all the managers summoned by the Offices, even coming from Ireland and South Africa; *ii*) the regulatory framework in force in the pharmaceutical sector in Italy should be in principle evaluated as a circumstance that can have favoured the conduct; *iii*) it adopted a specific antitrust compliance programme at global level.

399. With reference to the undertaking's effective collaboration, it is not deemed that Aspen collaborated beyond what required by obligations of law, nor that said collaboration resulted to be "*so effective to make the task easier for the competent antitrust Authority in ascertaining the infringement or inhibit it.*"<sup>246</sup> Nor is it deemed that, in the light of the considerations exposed above, the regulatory framework in force can have favoured, eased or authorised the infringement.

400. With reference to the Party's last request, it is hereby observed that the Aspen group adopted a compliance programme at worldwide level before the launching of the proceedings, then integrated in May 2015 with the updating of the training activities also to adjust the programme to the needs of the single Countries in which the multinational has its premises, promoting the implementation of "local face-to-face training" and the adaptation of the territorial programme to specific business areas in which the employees target of the training operate.<sup>248</sup> Said programme envisages the involvement of the management, the identification of the personnel in charge of the programme, the organisation of training activities, monitoring and auditing systems. It is hereby specified that, although the programme was adopted before the launching of the proceedings, the circumstance that it was broadened in May 2015, as well as the peculiarities of the exploitation abuse described, allows Aspen to be recognised, as extenuating circumstance and in line with what provided for by point 23 of the Guidelines, a [5-10]% reduction of the basic amount of the sanction, thus equal to [100,000-500,000] Euros.

401. The amount of the sanction, as established up to here, was then increased in the measure of [10-15]%, on the basis of what provided for by paragraph 25 of the Guidelines (the so-called overall size fee), so as to guarantee the dissuasive effect of the sanction, taking into consideration that Aspen has a particularly high global turnover (€ 2,212,500,000), way above the sales of the product to which the infringement refers (€ [5,000,000-10,000,000]). Therefore, the sanction, increased of [100,000-500,000] Euros, results to be equal to 5,225,317 Euros.

402. In conclusion, recalling point 29 of the Guidelines, the determined sanction does not exceed the maximum established, as mentioned under article 15, paragraph 1, of Law No. 287/1990.

Therefore, the Authority hereby

#### RESOLVES AS FOLLOWS

a) Aspen Pharma Trading Ltd., Aspen Italia s.r.l., Aspen Pharma Ireland Ltd., Aspen Pharmacare Holdings Ltd. carried out an abuse of dominant position infringing article 102, letter a), TFUE, consisting in the imposition of unfair prices for the commercialisation in Italy of Leukeran (2 mg – 25 tablets), Alkeran (50 mg/10 mg powder and solvent for injectable solution – 1 vial), Alkeran (2 mg – 25 tablets), Purinethol (50 mg – 25 tablets), Tioguanine (40 mg – 25 tablets), realised through a distorted and instrumental exercise of the right to negotiate prices with AIFA;

b) Aspen Pharma Trading Ltd., Aspen Italia s.r.l., Aspen Pharma Ireland Ltd., Aspen Pharmacare Holdings Ltd. must carry out all which is necessary to define fair prices with reference to drugs Leukeran (2 mg – 25 tablets), Alkeran (50 mg/10 mg powder and solvent for injectable solution – 1 vial), Alkeran (2 mg – 25 tablets), Purinethol (50 mg – 25 tablets), Tioguanine (40 mg – 25 tablets) and must not carry out future behaviours analogous to those object of the infringement ascertained above;

c) Aspen Pharma Trading Ltd., Aspen Italia s.r.l., Aspen Pharma Ireland Ltd., Aspen Pharmacare Holdings Ltd., within 60 days from the notification hereof, must communicate to the Authority the initiatives carried out to fulfil what required by the previous letter b), providing specific written report;

d) Aspen Pharma Trading Ltd., Aspen Italia s.r.l., Aspen Pharma Ireland Ltd., Aspen Pharmacare Holdings Ltd., on the basis of the seriousness and duration of the infringement, are imposed a total fine equal to 5,225,317 Euros (five million two hundred twenty-five thousand three hundred and seventeen thousandths Euros).

The administrative sanction as mentioned under the previous letter d) must be paid within ninety days from the notification of the resolution hereof, using the tax codes indicated in the annexed F24 form providing identification elements, as mentioned under Legislative Decree No. 241/1997. The payment must be carried out via computer with debit on personal bank or postal account, through the home-banking and CBI service put at disposal by banks or Poste Italiane S.p.A., that is using the IT services of the Agenzia delle Entrate, available at the website address [www.agenziaentrate.gov.it](http://www.agenziaentrate.gov.it).

<sup>246</sup> [Cf. Council of State, ruling n. 4506 of 4 September 2014, 1722 – International logistics (Albini & Pitigliani); Council of State, ruling No. 28383 of June 2014, 1722 – International logistics (Rhenus logistica).]

<sup>248</sup> [Doc. 213, annexes 26 A, 27, 28 and 29.]

Once said deadline is expired, in case of a delay not above six-months, interest on arrears must be paid according to the legal rate starting from the day after the expiry of the payment term and up to the payment date. In case of a further delay, pursuant to article 27, paragraph 6, of Law No. 689/81, the amount owed for the sanction imposed shall be increased by one tenth for each six-month period starting from the day following the expiry of the payment term and up to that in which the amount is paid; in said case, the increase absorbs the interests on arrears matured in the same period. The Authority is to be informed immediately of the payments carried out, by sending a copy of the form proving the occurred payment.

Pursuant to article 26 of the same law, undertakings that are in difficult economic conditions can submit a request to pay the fine through instalments.

This measure shall be notified to the subjects involved and published in the Italian Competition Authority's Bulletin.

Opposing the provisions hereof, an appeal can be lodged at the TAR of Lazio, pursuant to article 135, paragraph 1, letter b), of the Code of Administrative Procedure (Legislative Decree No. 104 of 2 July 2010) within sixty days from the date of notification of the provisions hereof, without prejudice to further terms as mentioned under article 41, paragraph 5, of the Code of Administrative Procedure; specifically, an extraordinary appeal can be submitted to the President of the Republic, pursuant to article 8, paragraph 2, of the Decreto del Presidente della Repubblica No. 1199 of 24 November 1971, within one hundred and twenty days from the date of notification of the provisions hereof.

THE SECRETARY GENERAL  
*Roberto Chieppa*

THE PRESIDENT  
*Giovanni Pitruzzella*