UNIVERSITÀ POLITECNICA DELLE MARCHE
FACOLTÀ DI ECONOMIA "GIORGIO FUÀ"

Corso di Laurea Magistrale in International Economics and Commerce
Curriculum: Business Organization and Strategy

ABUSE OF DOMINANT POSITION IN THE PHARMACEUTICAL SECTOR: THE ASPEN CASE

Relatore: Chiar.mo
Prof. Nicola Matteucci

Tesi di Laurea di:
Giovanna Urbanelli

Anno Accademico 2018 – 2019

TABLE OF CONTENTS

ABSTRACT

È un dovere dello Stato quello di intervenire in economia al fine di prevenire o risolvere fallimenti del mercato che possano ledere le naturali logiche competitive o danneggiare i consumatori finali.

È questo il caso del settore farmaceutico nel quale lo stato, inteso come insieme di apparati pubblici centrali e locali, non può decidere unicamente sulla base di norme imperative, ma deve tener conto di principi costituzionalmente garantiti.

A tal proposito, si discorre di un importante caso: l'iniquo aumento esponenziale del prezzo di vendita di alcuni farmaci salvavita prodotti dall'Aspen Pharma Holdings Limited.

L'azienda sudafricana, leader nel mercato rilevante, è stata formalmente accusata dall'AGCM, attraverso l'intervento del regolatore dei prezzi AIFA, di avere abusato della sua posizione dominante allo scopo di conseguire extra-profitti.

Per le ragioni sopra evidenziate, è necessario indicare le attività dell'autorità antitrust in un mercato competitivo, con lo scopo di definire le politiche e le analisi metodologiche del prezzo.

La difesa di un diritto inalienabile, quale quello del paziente a ricevere cure necessarie, diviene una problematica aleatoria per l'attività dello Stato "regolamentatore".

INTRODUCTION

The purpose of this thesis is to carry out an analysis of the antitrust theory and the abuse of dominant position, especially addressed to the Aspen case.

Since this is a significant pharmaceutical case, the main objective is to study market regulation. In particular, we will describe the price regulator in Italy, AIFA, in order to approach the issue of prices and purchase of medicines.

To recognize the abuse of dominant position we will analyse the Antitrust theory.Firstly, the phases of the development of the discipline should be investigated through: the relevant market in which it operates; the main pillars of the Antitrust theory and the national and international interaction plans. Furthermore, we will treat the Antitrust globally, from historical to the normative background, so as to introduce the discipline in the Italian scenario.

The body that covers the role of the Antitrust Authority in Italy is the AGCM, which has denounced and dealt with several behaviour of abuse of dominant position. As regards this issue, in a competitive market, which can often be the reason of these unlawful behaviours, regulation and agreement between the partiesrequire a guarantee of the legitimacy of actions.

Regarding these aspects, the Aspen case is aprime example to analyse.

Before verifying how the multinational has acted illegally, we will focus on the holdings that interact in the European market. In fact,throughout the continent,the

Aspen Pharmacare Holdings Limitedhas operational offices, which interface with each other for the purpose of determining the prices of the products andmaking a deal with other pharmaceutical companies.

In detail, we will illustrate how Aspen has acted against the *Servizio Sanitario Nazionale* and consequently theconsumers. This analysis will take as benchmark the measurement of costs, the determination of prices and the estimation of unfairness.The research for practices of abuse of dominant position will be at the base of the whole proceeding.

Furthermore, AIFA and AGCM play a key role in the case, that is why we will investigate when and how Antitrust could "save lives".

From a legislative and regulatory standpoint, the relevant market of Aspen Case will be studied, taking similar case studies as an instance, in order to outline how the Authorities, behave in different European countries.

To demonstrate that some unfair practices damage the proper functioning of society, we will focus on the inalienable human right: the right to life.

Last but not least, we will accomplish the economic analysis. In particular, we will evaluate the policy of medicinal products, studying the new manual of drugs and the governance of prices. Moreover, we will report the transparency of prices in the Italian background with deeds and testimonies of the major exponents of the industry.

So as to understand the decisions of the parties participating in the Aspen case, we will discuss the aspects that could damage the functions of a competitive market. In detail, we will try to match the conflict of interest and the information asymmetry with the actions of the participants: we will wonder if Aspen case's operations have been carried out according to these practices. Besides, the aspects of monopoly will be highlighted, stressing the inefficiency in the pharmaceutical sector.

Finally, we will consider the methodologies used to analyse the conduct of the Aspen Pharmacare as well as the analysis of the data provided by the Authority, so that whether the price increase may be unfair.

1 CHAPTER: ANTITRUST AND ABUSE OF DOMINANT POSITION

1.1.INTRODUCTION

In the following chapter the Antitrust theory and the abuse of dominant position will be analysed.

Starting from a brief introduction, we will move on to the study of the pharmaceutical market: in particular, it will be treated the bodies responsible of the operations, such as AIFA; the logic of drug purchases and the regulation of medicines' prices.

Subsequently, in a detailed manner, we will talk about the Antitrust theory, including the analysis of the relevant market, the pillars of the Antitrust framework and the interactions between national and international plans.

Finally, the Italian Antitrust will be discussed, explaining the AGCM, the abuse of dominant position and the competition.

Deepening, in the drafting of the following chapter, it is recognized that, in the capitalist context, the need for a device to control economic power arose: that is Antitrust.

The purpose is to protect consumers and to respect the rights of the citizen as it is often concerned with safeguarding life itself.

In fact, this trend refers to the industrial sector, which in our case are interventions aimed at protecting and promoting competition in the pharmaceutical sector.

1.2.REGULATION OF PHARMACEUTICAL MARKET

In the previous paragraph the main principle was highlighted, according to which the consumer has the right to the effective availability of pharmaceutical treatments. Therefore, the efficacy of therapiesis devoid of any form of recklessness.

In the case of lack of transparency, the leaders of nations may incur a prejudice to the condition of development and they may undermine public health: for this reason, regulation in the pharmaceutical sector was necessary.

Starting from article 1 of the legislative decree of 24 April 2006, n.219(Decreto Legislativo 24 aprile 2006, n. 219, 2006)[1], some definitions are required for the Community Code concerning medicinal products for human use.

In particular, from paragraph "a" it is noted that "*medicine*" means any substance or form of substance that has healing or disease prevention properties and possesses the purpose of restoring, correcting or modifying physiological functions.

[1]Retrieve from: (http://www.camera.it/parlam/leggi/deleghe/06219dl.htm)

Furthermore, mass production and the advent of new technologies has led to increased drug availability. Consequently, another identified problem is that of a pharmacological squandering, which can be harmful to the patient.

A phenomenon was recognized in the early years of the twentieth century under the name of *patent medicines*[2], which indicated the medicines that would mimic patents or official licenses to guarantee healing properties. These medicines were often sold through "*medicine shows*" and thereforelegislators were forced to introducenew quality and safety verification measures[3].

A greater deepening of the regulation of the sector and the competent authorities is given to batches from the second half of the nineteenth century: drugs reached large numbers and direct control over the conduct of the field became extremely difficult.

In response, an institution was established in 1946 entitled the *World Health Organization*[4] (WHO), headquartered in Geneva. However, despite being considered as special agency of the United Nations, the WHO does not formally have binding powers to manage health policy: its pursue is dedicate to the management of healthcareemergencies.

Furthermore, the work of the WHO is not aimed at private interlocutors, from which the availability of pharmaceutical instruments starts; rather it interfaces

[2]Retrieve from: [https://dictionary.cambridge.org/us/dictionary/english/patent-medicine].
[3] "*La cura della concorrenza*", L. Arnaudo, G. Pitruzzella. 2019, pp. 17-18.
[4]Retrieve from: [https://www.who.int/].

with public and institutional environments. For this reason, over the course of time, macro-regional or small-scale regulatory skills have had to work alongside the institution to solve problems of a global nature.

Specifically in the European setting, the *European Economic Community*(ECC)[5],following the tragedy of thalidomide[6], introduced a discipline in order tofavour the convergence of pharmaceutical regulations in force in the various Member States.

This ruleis contained in *Directive 65/65/ EEC [i.e. chapter 2,* Authorization to place medicinal products on the market*,Article 3: "No medicinal product may be placed on the market of a Member State unless a marketing authorization has been issued by the competent authorities of that Member State in accordance with this Directive or an authorization has been granted in accordance with Regulation (EEC) N. 2309/93 of 22 July 1993[7]"].*

[5]In 1957, the Treaty of Rome creates the EuropeanEconomic Community (EEC), or 'Common Market. [https://europa.eu/european-union/about-eu/history_en]. Upon the formation of the European Union (EU) in 1993, the EEC wasincorporated and renamedas the European Community (EC). In 2009 the EC'sinstitutionswereabsorbedinto the EU'swiderframework and the community ceased to exist.

[6]Thalidomidewas a widelyuseddrug in the late 1950s and early 1960s for the treatment of nausea in pregnantwomen. Itbecameapparent in the 1960s thatthalidomide treatment resultedbirthdefects in thousands of children. Though the use of thalidomidewasbanned in mostcountriesatthat time [see https://academic.oup.com/toxsci/article/122/1/1/1672454].

[7]Retrievefrom:[https://www.echamp.eu/eu-legislationandregulationdocuments/directive_65-65-eec__-__consolidated_version.pdf]

This process of uniformity then evolved into the *Treaty on the Functioning of the European Union* (TFEU)[8] and the mainstay of European pharmaceutical legislation is currently constituted by Directive 2001/83/EC[9] and Directive 2003/94/EC[10].

Following lengthy negotiations between the member States of the Union, a special Authority, the*European Medicines Agency* (EMA), was introduced to accompany the relevant administrative activities at the European Union level.EMA was established pursuant to regulation 726/200/EC[11] and it is intended to supervise the approval of most drugs distributed in the EU through a centralized procedure concerning safety, efficacy and product availability in a single European market. The introduction of this authority has also led to a positive aspect for pharmaceutical companies, as they have only one interlocutor to be referred[12].

[8] The TFEU originatedas the treatyestablishing the EuropeanEconomic Community (the EEC treaty), signed in Rome on 25 March 1957. On 7 February 1992, the Maastricht treaty, which led to the formation of the European Union, saw the EEC Treatyrenamedas the Treatyestablishing the European Community (TEC) and renumbered. On 13 December 2007 the Lisbontreatywassigned. Thissaw the 'TEC' renamedas the Treaty on the Functioning of the European Union (TFEU) and, once again, renumbered. The Lisbonreformsresulted in the merging of the threepillarsinto the reformedEuropean Union.

[9]Retrieve from: [https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/directive-2001/83/ec-european-parliament-council-6-november-2001-community-code-relating-medicinal-products-human-use_en.pdf].

[10]Retrievefrom:[https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32003L0094].

[11] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32004R0726

[12] "*La cura della concorrenza*", L. Arnaudo, G. Pitruzzella. 2019, pp. 19-21.

1.2.1. AIFA

The reference body in Italy is the *Agenzia Italiana del Farmaco* (AIFA). It was established starting from the decree law of 30 September 2003, n. 269[13]:it is described in paragraph 2 of CHAPTER IV : "*agreement regional state in healthcare*" art. 48 (Cost of pharmaceutical assistance), which cites: "*Without prejudice to the fact that the drug is a tool for health protection and that the medicines are provided by the National Health Service as they are included in the essential levels of assistance, in order to guarantee the unity of the pharmaceutical activities and to favour in Italy the investments in research and development, the Agenzia Italiana del Farmaco, hereinafter referred to as the Agency, is established with effect from 1 January 2004, subject to the direction of the Agenzia Italiana del Farmaco supervision of the Ministry of Health and the Ministry of Economy and Finance*".

Among the functions listed, there most relevant are: the regulation of the pharmaceutical sector and the security controls to residual drugregistration procedures. In addition, the institution also deals with the negotiation of prices and the methods of reimbursement of the products to be applied in the pertinent regulation.

These functions are the consequence of the pricepolicies adopted by the European Union, which we will analyse later.

[13]Retrieve from: [http://lexitalia.it/leggi/dl_2003-269.htm]

1.2.2. Drugs purchase

The research and development activities of a drug are fundamental to defining a reference model. Usually the respective authorities that act as the first reference pointsof the the companies are the FDA[14] and the EMA[15]. However, it is important to highlight the legal and economic research for a respective drug.

There are several stages in the development of a medicine, which usually they request a span of five and ten years for the final product.

The first phase includes studies conducted on a limited number of healthy volunteers to establish tolerated dosage of a medication. The second is called "*explorative-therapeutic*" and it is aimed at better understanding the ability of activity against a particular pathology. At this stage the combination of the scientific and commercial path begins, and the drug is also given a name by the pharmaceutical company for the recognition in the market.

At the end of the second phase, if the drug had a positive feedback in terms of benefit/risk the medicine continues to third phase. This is called "*therapeutic-confirmatory*", in which a clinical study conducted on a large number of patients is designed to compare the drug to existingone for understanding the benefits of the new product compared to standard of care therapies.

[14]Food and Drug Administration, a federal agency of the UnitedStatesDepartment of Health and Human Services.

[15] The EuropeanMedicines Agency, a European Union agency for the evaluation and supervision of medicinalproducts.

According to a recent study by the OECD[16], in the case of an anticancer drug, the success rates would be 5.1% in the first phase, 8.1% in the second and 33% in the third phase.

Subsequently, after demonstrating that the drug in question conforms to efficacy and safety, the company submits to the aforementioned competent authorities, the FDA and the EMA, a file containing the overall data of the research. Regulatory bodies then issue a marketing authorization (AIC) with the title of marketing rights, which is called the *Marketing Authority Holder* (MAH).

After the introduction into the market, the drug becomes identifiable thanks to the attribution by the WHO of a non-proprietary name (*International Non-proprietary Name*, INN) which refers to the active ingredient.

The fourth phase concerns post-marketing, better known as "*pharmacovigilance*". This is carried out by the drug agencies and the MAH.

Finally, for all new drugs on the market, it is necessary to attach a booklet of instructions useful to the consumer; in the EU it is called the "*summary of product characteristics*"[17].

[16]Organisation for Economic Co-operation and Development.
[17] "*La cura della concorrenza*", L. Arnaudo, G. Pitruzzella. 2019, pp. 22-26.

1.2.3. Regulation of drug prices

The determination of drug prices considers several factors, which can be summarized in four main aspects: the law governing the bargaining model of the price, with the attention on AIFA; the reflections on the price of constraints in terms of programming of heath spending; the regulations concerning drug's patent and binding rules for contracts off purchase and supply reimbursable drugs.

As a rule, price regulation is determined by the value that the State pays so that the citizenscan request its use. The consumer relies on a doctor or pharmacist to identify which medicine is best suited to treat a particularhealth condition.

Usually the classification of the medicine affects who should pay for the drug. In order to determine who is the "payer", among the categorization, there are for instance "*class A*" drugs , which obtains a refund, following an evaluation, by the *Servizio Sanitario Nazionale(SSN*[18]*)*.

Exactly, in order to rationalize pharmaceutical expenditure in 1994, law n. 5374 was introduced, in which the *Commissione Unica del Farmaco* (CUF)[19] was assigned the task of placing medical specialties in a new handbook organized in three classes. The first, as mentioned above, is *class A*, which concerns essential drugs and chronic diseases. The costs are fully borne by the SSN. The second is

[18] The Servizio Sanitario Nazionale (SSN), established by Law No. 833 of 1978, provideshealth care to allcitizenswithoutdistinction of gender, residence, age, income and work.
[19]Retrieve from:http://www.salute.gov.it/imgs/C_17_pubblicazioni_250_allegato.pdf

the *class B*[20], which includes the drugs for less serious pathologies and the costs of which are supported partly also by the consumer. Finally, *class C*, which includes drugs totally paid for the patient.

With regard to the Italian situation, the SSN expresses a significant market force: compared to a total pharmaceutical expenditure close to 30 billion euros per year, the one entirely borne by the SSN, through the reimbursement methods, is more than 22 billion euros per year.

These data are considered relevant from a commercial point of view. In many cases there is illicit monopoly exploitation and the interruption of procurement procedures by the public administration, since they are inefficient in the case of competition. In fact, situations have been reported in which preferential treatment is the basis of many agreements and according to the legislative regulation this is not allowed.[21].

In an Italian context, the introduction on the market and the relative classification of the products by the SSN belongs to the Italian Medicine Agency, AIFA.

[20] Class B, starting from 1 July 2001, from the art. 85 paragraph 1 of the law of 23 December 2000, n. 388, hasbeensuppressed; while a new classcalled C-bis hasbeenintroduced: thatis, non-prescriptiondrugs, alsoavailable in parapharmacy.

[21] "*La regolazione dei prezzi dei farmaci*", Rivista della regolazione dei mercati, Monica Delsignore, 2014, pp 192-194.

The classification in this case is quite similar to the previous one and the reference legislation is that of Article 48, paragraph 33, of the Law of 24 November 2003, n. 326[22].

In Italy, all drugs that are essential for chronic diseases fall under *class A*, with no charge for the total burden of the state. The other is the *class H*, that is all the products borne by the state, with a possible specialized distribution in pharmacies (they refer to PHT[23] products). Finally, there is the *class C*composed of drugs that are not part of the first two classes. These drugs are totally charged to the consumer since they are freely available for purchase, called over the counter, or "OTC".

In 2012 a new sub-category was introduced, the "*Cnn*", meaning "non-negotiated" with the aim of allowing the immediate availability of a drug in the market and which could be negotiated in the future for reimbursement by the Servizio Sanitario Nazionale. In addition to this new category, there have been lengthy negotiations to reach agreements between AIFA and the AIC.

Finally, another important issue is: in Italy, due to the presence of AIFA and adirective based on transparency, negotiations between drug agencies and

[22]Retrivedfrom:[https://www.gazzettaufficiale.it/eli/gu/2003/11/25/274/so/181/sg/pdf]
[23] PHT, the Handbook of directdistribution for the care and continuity of the Hospital-Territory

companies are more facilitated and there is no required to have strategic complexities that can make price comparison difficult and supply conditions.[24]

1.3.ANTITRUST THEORY

Competition is one of the great forces that animate human society, in particular in the background of business activity. Competition increases human performance, which improves well-being for individuals and for the community.

Proving the importance of this discipline, for centuries, the actors, that are part of the economic context, must try to coordinate the difficulties in which they incur and the actions in an ethical and professional way. As a result, over the years, legal systems had to adopt new complex disciplines, so that commercial behaviour can be respected.

In the historical framework, a first reference to the Antitrust discipline is the "*Sherman Act*[25]", which aim was toprevent more companies from agreeing with each other prices and other commercial conditions, but above all to forbid individual companies from exploiting their dominance cheap.

In the other side, at the Pan-European level there were several disciplines that were established, first the ECSC Treaty in 1952, then the EEC Treaty in 1957, which remains the basis of the current TFEU.

[24] "*La cura della concorrenza*", L. Arnaudo, G. Pitruzzella. 2019, pp. 41-43.

[25] The Sherman Antitrust Act, or "ShermanAct" of 1890 is a UnitedStates antitrust law thatregulatescompetitionamongenterprises, whichwaspassed by Congress under the presidency of Benjamin Harrison.

Recently, in his work "*Towards A Broader View of Competition Policy*[26]", published in 2017, Joseph Stiglitz[27]stated that the competition policy (Antitrust) *"began in the United States as a political agenda, to limit the market and political power of trusts (monopolies and oligopolies). Of course, long before that, economists had recognized that competition was necessary if the market economy was to achieve efficient outcomes, and that firms on their own strive to limit competition. Market power has, of course, distributive effects as well. Monopolies' decisions are to the detriment of consumers: as monopolies raise their prices, their profits increase while the well-being of consumers and workers decrease. An increase in market power is associated with an increase in inequality"*.

This interpretation shows the irregularity of the practicein many economic and social situations and over time there have been different interpretations, emphasizing the importance to safeguard economic freedom.

This is demonstrated in terms of greater availability of goods and services, as well as lower prices obtained through competitive comparison between companies.

From the operational point of view, this process together with the economic one has been matched by the expression "*public enforcement*", contrary to the

[26]Retrievedfrom:[https://rooseveltinstitute.org/towards-broader-view-competition-policy/, page 3]

[27] Joseph Eugene Stiglitzis an American economist, public policy analyst, and a professor at Columbia University. He is a recipient of the Nobel MemorialPrize in EconomicSciences (2001) and the John Bates Clark Medal (1979).

disputes conducted by private individuals to reach their own interests, which is defined as "*private enforcement*".

Public bodies entitled to the protection of the public interest in competition are usually independent agencies with executive power; however, there are two Antitrust government branches recognized worldwide: The*Federal Trade Commission* (FTC) and the *General Directorate of Competition of the European Commission*.

More specifically, the Federal Trade Commission (FTC) was established in 1914 with the "FTC Act" and it refers to the US environment.

The civil and criminal actions provided for the "Sherman Act" have remained exclusive to the Department of Justice (DoJ) and individual state prosecutors.

In the other side, the Antitrust law of the General Directorate of Competition of the European Commission ("Commission") concerns the European environment. It is a technical body under the guidance of a special competition commissioner.

The control of these two Antitrust laws is held by the highest magistrates, the US Supreme Court[28], for the first one and the EU Court of Justice[29], for the second one.

[28] The Supreme Court began to take shape with the passage of the JudiciaryAct of 1789 and hasenjoyed a richhistorysinceits first assembly in 1790, retrieved from: [https://www.supremecourt.gov/about/historyandtraditions.aspx]

[29]Based in Luxemburg, hastwosectionscalled "General Court" and "Court of Justice", retrieved from: [https://curia.europa.eu/jcms/jcms/j_6/en/]

1.3.1. Relevant market

In an Antitrust judgment phase, it is necessary to define the relevant market, i.e. a field of observation in which the company operates.

As a rule, it consists of delimiting the smallest possible context against which to ascertain the conduct of the company, in particular what concerns their "market power".

The delimitation of a relevant market takes place mainly through the analysis of the substitutability of products among consumers. In this way it is possible to establish the extent of competitive alternatives available in consumption choices.

In our case, the sector that it has to be analysed is the pharmaceutical sector.

In detail, the substitutability analysis refers to the subdivision of the drugs according to the therapeutic classes identified by a specific index: "*Anatomical Therapeutic Chemical Classification Index*" (ATC). Basically, from their presence in the same class in therapeutic use, their substitutability is derived from the commodity point of view.

Obviously, judgment of substitutability between products includes administrative, distribution-commercial and advertising considerations[30].

[30] "*La cura della concorrenza*", L. Arnaudo, G. Pitruzzella. 2019, page 55.

1.3.2. Pillars of Antitrust discipline

The conduct of a company can be defined according to three main types od Antitrust decision, better knows as pillars: agreements between competing companies that affect the production and distribution efficiency expected from the competition; abuse of market position of a company; and finally, excessive concentrations of economic power pursued through mergers and acquisitions of companies.

Concerning the agreements in the first pillar, the Antitrust law deals with the illegal ones. In fact, there are several regulations that attempt to undermine this type of behaviour. Starting from article 1 of the "*Sherman Act*", which establishes "*illegal any contract, combination in the form of trust or other form and conspiracy aimed at limiting trade or commerce between the States[USA] or with foreign nations*"; ending with article 101of TFEU.

The latter, and in particular the first paragraph, has a more detailed regulation, that mentions: "*The following shall be prohibited as incompatible with the internal market: all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the internal market, and in particular those which: (a) directly or indirectly fix purchase or selling prices or any other trading conditions; (b) limit or control production, markets, technical*

development, or investment; (c) share markets or sources of supply; (d) apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage; (e) make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts[31]".

The second pillar is given by the unilateral control of companies consisting of abuses of a dominant position, or the undue exploitation of its market power.

In this case, the main normativeare article 2 of the "*Sherman Act*" which prohibits any attempt to acquire market power unduly; and article 102 of TFEU.

In this case the law offers an express list of prohibited conduct, that is: "*Any abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it shall be prohibited as incompatible with the internal market in so far as it may affect trade between Member States. Such abuse may, in particular, consist in:(a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions; (b)limiting production, markets or technical development to the prejudice of consumers;(c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;(d) making the*

[31]Retrieve from:
[https://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12008E101:EN:HTML]

conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts[32]."

The third and final pillar of the Antitrust framework is the control of concentrations. It refers to an *ex ante* judgment, therefore in advance with respect to concentrations of market power that will be produced in the head of a company and it will be considered excessive with respect to a healthy competitive balance.

In the case of the EU, the legislation on the control of concentrations is the EC regulation n. 139/2004[33].

1.3.3. National and international plan interactions

The EU environment has an unusual situation: despite the regulations of articles 101 and 102 of the TFEU, among the characteristics of the EU order, there is the possibility that the authorities of the Member States autonomously apply the EU competition law.

Further, the national Antitrust Authorities can choose the national legal basis to be adopted for their own proceedings.

However, there is specific legislation that is cautious, in order to continue the uniform application of the law and the coordination of the activities of the

[32]Retrivedfrom:[https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:12008E102]
[33]Retrivedfrom:[https://eurlex.europa.eu/legalcontent/en/ALL/?uri=CELEX%3A32004R0139]

authorities placed on different operational plans. To this purpose, there is a coordination between the national Antitrust Authorities and the Commission (article 3 of EC Regulation no. 1/2003[34]).

Independently the coordination between national and international plans, especially in the pharmaceutical field, the issue remains that there is necessity of a discipline of competition on a global scale. That is why the competitive dynamics and the possible infractions are global, so even their control and contrast should be emphasized[35].

1.4.ANTITRUST IN ITALY

Within the European Union, as already discussed, the attention of the Antitrust authorities in the pharmaceutical sector has focused on the issue of parallel medicines imports. A series of agreements have been developed to control trade flows between Member States with the aim of developing a single market.

The history of the Antitrust law in Italy formally began with the law of 10 October 1990, no. 287, which in the field of application cites: "*The provisions of this law in implementation of Article 41 of the Constitution to protect and guarantee the right to economic initiative, apply to agreements, abuses of dominant position and concentrations of companies that they do not fall within the scope of Articles 65 and / or 66 of the Treaty establishing the European Coal*

[34]Retrivedfrom:[https://eurlex.europa.eu/legalcontent/IT/TXT/?uri=CELEX%3A32003R0001]
[35] "*La cura della concorrenza*", L. Arnaudo, G. Pitruzzella. 2019, pp 62-64.

and Steel Community, Articles 85 and / or 86 of the Treaty establishing the European Economic Community (EEC), Community regulations or Community acts with equivalent effect[36]".

It is important to emphasize that there is an independent authority to protect the competition and the consumer: which is The Italian Competition Authority (Italian: *Autorità Garante della Concorrenza e del Mercato*, AGCM).

1.4.1. AGCM

The Italian Competition Authority is an administrative independent Authority, established by Law no. 287 of 10 October 1990 ("*The Competition and Fair Trading Act*", hereinafter "the Act"), which introduced Antitrust rules in Italy. Nevertheless, subsequent laws endowed the Authority with additional powers: the most important of which concern the repression of unfair commercial practices, but also cares misleading and unlawful comparative advertising and the application of conflict of interests laws to government-office holders.

Being an independent Authority, it has the status of a public agency whose decisions are taken on the basis of the Act without any possibility of interference by the Government.

The Authority's independence is reinforced by the appointment procedures and prerequisites of its chairman and of three Members. They remain in office for a

[36]Retrieve from:
[https://www.gazzettaufficiale.it/eli/id/1990/10/13/090G0340/sg]

sevenyear with non-renewable terms and they are jointly appointed by the Presidents of the Chamber of Deputies and Senate. The prerequisite for the Chairman isto have a reputation for independence as well as service in other high-level institutional positions. The Members are selected from amongst the magistrates of the State Council, the Court of Auditors and the Court of Appeals, all of university professors of economics or jurisprudence and outstanding personalities from the economic sector with impeccable reputations.

This collegiate body, the Board, makes its decisions by majority rule. It currently consists on the Chairman, Roberto Rustichelli (appointed on 6 May 2019) and two Members: Gabriella Muscolo (appointed on 16 May 2014) and Michele Ainis (appointed on 08 March 2016). The Secretary General of the Antitrust Authority, Filippo Arena, supervises operational and office management[37].

In the pharmaceutical sector, the AGCM undertook various interventions in the 1990s, as shown by some investigative procedures concerning anti-competitive agreements, relating to parallelisms of prices considered illegal.

However, starting from early 2000's, the AGCM has shown for the first time specific attention to the pharmaceutical industry, in particular due to the exclusive possession of patents and their effects on competition. For instance, in 2005 the AGCM took over two preliminary proceedings: The Glaxo and Merck cases.

[37]Retrieve from: ABOUT US[https://en.agcm.it/en/about-us/]

Both cases concerned the refusal of the request to obtain a license for its production, opposed by a company that owns the exclusive patent rights on the active ingredient of the drug[38].

This production was intended for the sale of the active ingredient to third-party pharmaceutical companies, which were bound to become generic versions distributed outside Italy.

By imposing the urgent release of a license, the AGCM has acknowledged that only the immediate release of the limitation to the production of the active principle would have allowed to obtain positive effects on competition[39].

1.4.2. Abuse of dominant position in Italy

The issue of patent abuse has found expression in another AGCM proceeding, initiated in October 2010 and concluded in January 2012 against companies belonging to the Pfizer group. According to the Authority, the group has committed an abuse of a dominant position in order to unduly protect the commercial exclusivity of its own medicine.

The product at the centre of the background is the Xalatan[40], which has quickly acquired a position of absolute dominance, becoming the commercial status of blockbusters.

[38] AGCM, proc. A363-Glaxo Principi Attivi, provv. N. 15175 dell'8 febbraio 2006. A354-Merck-Principi Attivi, provv. N. 16597del 21 marzo 2007, provv. N. 14388 del 15 giugno 2005.
[39] "*La cura della concorrenza*", L. Arnaudo, G. Pitruzzella. 2019, pp 101-105.

Initially the intellectual property of the product belonged to Pharmacia[41], a company that the Pfizer group acquired in 2003. As a result, the Pharmacia group requested a divisional patent from EPO[42], aimed at protecting different claims on the active ingredient "latanoprost". Subsequent to the takeover, Pfizer also ensured that the patent was validated in Italy and in this way the expiration of the exclusivity on Xalatan was recognized until 2011. From this deal, the first allegations of abuse of dominant position started by part of other pharmaceutical companies that could not use the active ingredient, in particular the German company Ratiopharm[43]. It entered a drug equivalent to Xalatan into the business and it sent a report on the alleged abuse of dominant position to the AGCM.

The conviction and the simultaneous warning to abstain from similar behaviour in the future ended with a sentence by the State Council in February, 2014.

The highest administrative court qualified the abuse of dominant position committed by Pfizer as a specification of the broader category of abuse of law. It has established a legislative recognition in the EU system, with the article 54 of

[40]Xalataneyedrops, whichcontainprostaglandinlatanoprostas an activeingredient, are used to lowerintraocular pressure in open-angle glaucoma and in cases of elevatedintraocular pressure. High intraocular pressure can damage the opticnerve and lead to impairedvision.

[41] Pharmacia was a pharmaceutical and biotechnological company in Swedenthatmerged with the American pharmaceutical company Upjohn in 1995.

[42]EuropeanPatent Office, as a patent office for Europe, theysupportinnovation, competitiveness and economicgrowththroughout Europe. [https://www.epo.org/about-us.html].

[43]Ratiopharmis a Germanpharmaceutical company thatisEurope'sleadinggenerics brand.

the Charter of Fundamental Rights of the Union, signed in Nice on 7 December 2000, "*Prohibition of abuse of rights*[44]".

Moreover, the impression offered a series of specific indications about the constituent elements of the abuse of the law, including: effective ownership of a right by a subject; possibility that the concrete exercise of law is not typified; surrounding for which the concrete exercise of the right took place according to censurable methods with respect to a "legal or extra-juridical" evaluation criterion; and finally, unjustified disproportion, resulting from the exercise of the right, between the benefit obtained by its owner and the sacrifice to which the counterpart is subjected[45].

1.4.3. Competition

In the field of competition, there is the law of 4 August 2017, n. 124, "*Annual law for the market and competition*", which contains provisions by which the Legislator intends to remove obstacles that prevent the opening of markets, in order to promote the development of competition and to guarantee consumer protection. Also this law aims for covering the application of the principles of European Union law on free movement, competition and market opening, as well as European competition policies[46].

[44]Retrieve from: [eurlex.europa.eu/legalcontent/IT/TXT/?uri=CELEX%3A12012P%2FTXT].
[45] "*La cura della concorrenza*", L. Arnaudo, G. Pitruzzella. 2019, pp 107-112.
[46]Retrieved from: https://www.periodicimaggioli.it/legge-n-1242017-settore-farmaceutico/

Competitions is necessary to determine how a market works. According to Popper's "*zero method*", market operations are not guided by the "*pure logic of choice*", which guides the decisions of agents almost always conditioned by empirical limitations. Rather, the markets are perceived as "*institutions*" that perform the function of facilitating production and consumption decisions because of the fact that they address the lack of knowledge and the limitation of the rationality of agents who want to realize their own interests. From this principle, a new border of research may be framed as "*behavioural economics*", which has been approached in cases of "*behavioural Antitrust*".

The focus of behavioural economics for Antitrust doctrines consists in understanding the function of economic institutions in real dominant environments, aimed at bringing out balances whereby the presence of a public institution is no longer so decisive.

However, there are objective limitations to rationality, since most of the real economic decisions are taken under conditions of uncertainty.

For these reasons, it is appropriate to underline the concept of competition*:"since it is the force that shapes the rationality of the agents, allows the achievement of the productive and allocative benefits commonly associated with market forces, exploits the profit opportunities generated by the imbalances*

facilitating convergence of individual expectations, and favours the tendential alignment of prices towards minimum production costs[47]".

The Anglo-Austrian economist and philosopher Friedrich August vonHayek defined competition as: "*not the only method known to use the knowledge and skills that others may have, but it is also the method by which it has come to buy much of the existing knowledge and skills [...] Competition makes it necessary to act in order to remain on the market. It is based on the principle according to which the most rational force others to emulate them [...] Therefore, in general, it is not rationality that is necessary for the functioning of competition, but it is the latter, and the traditions that encourage it, that produce rational behaviour*[48]".

However, as regards certain markets, it is necessary to have a clear and complex regulatory context, having to consider a plurality of elements and variables expressed by law and the economy. This can be applied to the pharmaceutical market, which has a relationship between Antitrust access to particularly important medicines.

In fact, a duly operating competition constitutes a powerful tool to guarantee the satisfaction of access rights to essential goods, such as drugs. The medicines are

[47] "*La natura dei mercati, l'economia comportamentale e l'antitrust*", Mercato concorrenza regole, Anno XX, n.2, agosto 2018, Antonio Cucinotta, p. 199.
[48] "*Legge, legislazione e libertà",* F.A. Von Hayek, Milano, 1989, pp. 449-450.

relevant because they rely on the concrete integration of the right to life and its more specific aspects, in particular the right to health.

A commission report by the ONU secretary general quotes: "*if governments paid more attention to competition law, this could serve as an important policy tool to expand access to health technologies*[49]*"*.

The memorandum of understanding between AIFA and the AGCM has a great importance, which: "*within the sphere of their respective competences, pursue convergent interests aimed at developing and maintaining adequate levels of competition in the markets, to protect consumers, to the 'access to drugs and to the economic equilibrium of the system in respect of the spending limits, so the aforementioned convergence of interests, while respecting the autonomy and independence of the respective functions, determines the opportunity to establish cooperative relations to coordinate and make the execution of their respective institutional mandates more effective and effective.This cooperation, in implementation of the general principle of loyal collaboration between institutions and in accordance with the principle of good progress of the administrative action pursuant to art. 97 of the Constitution, makes it necessary to share information and data acquired in the exercise of their respective functions and competences*".

[49] "*La cura della concorrenza*", L. Arnaudo, G. Pitruzzella, 2019, pp. 148-149.

This agreement was signed between Giovanni Pitruzzella, the former President of the AGCM, and the former general director AIFA, Mario Melazzini.

The priorities are to supervise in a more targeted manner and to act promptly against the phenomenon of counterfeit medicines and illegal sales of medicines online. A structured collaboration allowed the comparison and the exchange of documents and information between the institutions in all their operational areas, starting from the negotiation of medicine prices. The objectives of the agreement also include:an adequate levels of competition in the markets; the combat of unfair commercial practices towards consumers; and the protection patients and the Servizio Sanitario Nazionale[50].

[50]Retrieve from: [http://www.sanita24.ilsole24ore.com/art/dal-governo/2017-01-19/farmaci-e-concorrenza-patto-aifa-e-antitrust-112459.php?uuid=AE9XVZD&refresh_ce=1]

2 CHAPTER: ASPEN CASE

2.1 INTRODUCTION

In this chapter we will specifically focus on the analysis of the Aspen Pharmacare Holdings Limited case. This is a significant example of abuse of a dominant position, in whichit is demonstrated how antitrust Authority operated.

Firstly, we will explain the pharmaceutical company in order to have an overall vision of the Group. Progressively, we will consider all the parties of the multinational corporation involved in the proceeding, so as to understand in which way they acted.

In detail, we will illustrate the complaint of the counterpart, the disputes of the developments and the conclusion of the proceeding.

The measures of the costs, the composition of the price and the inequality estimates will be deepened, sincethey have been considered the underlyingstudy of abuse of dominant position.

Finally, the last paragraph of the chapter aims to study the legislative and regulatory situation, through the relevant market in the Aspen case, in order to elucidate what is the market position of the pharmaceutical company.

Moreover, through some examples provided by studies of similar cases, we will conclude by emphasizing how access to drugs is considered a right to life.

2.2. ASPEN PHARMACARE HOLDINGS LIMITED

Aspen Pharmacare Holdings Limited is a multinational pharmaceutical company, headquartered in Durban, South Africa. Its origins started with 160 years' heritage and its growth included a leading specialty and brand sector.

Indeed, the basket of products includes a wide range, such as pharmaceuticals, injectable, tablets, liquids, capsules, sterile, biologicals, active pharmaceutical ingredients, nutritional products, referring to acute and chronic considerations experienced in all stages of life.

The company maintains a focus on various therapeutic categories: thrombosis, anaesthetics, high potency and cytotoxic, and nutritionals.

Aspen Pharmacare Holdings Limited has a strong presence in both emerging and developed countries with 70 established business operations in approximately 150 countries[51].

As for the interim financial results for the six months ended December 31, 2018, they are in line with what the Group had proposed.

Regarding the market choices, Stephen Saad, Chief Executive of Aspen Group, stated that: "*The disposal of our Nutritionals business is nearing completion which will enable us to put all our focus on pharmaceuticals. We are conducting a strategic review of both our European and South African Commercial Pharma*

[51]ABOUT ASPEN "*Group Overview*", retrieved from: [https://www.aspenpharma.com/group-overview].

businesses and have already decided to split the latter into two distinct divisions to achieve heightened product and customer focus. The second phase of the South African review will focus on developing strategies specific to each division to optimise value delivery[52]*"*.

More specifically, from the positive results, in September, 2018 Aspen announced that it had reached an agreement for the sale of its activities in the nutritional sector to the Lactalis Group[53].

Despite some hindrances, the parties worked on the bargain for defining a closing date. The activities, related to the Nutritionals business, have become profitable sales.

Furthermore, Aspen has signed agreements relating to the sale and termination of a non-core pharmaceutical portfolio in the Asia-Pacific region. The assets relating to the above-mentioned portfolio have becomesource of income[54].

The Group has an approach to sustainability, concentrating its daily themes and activities on this principle.

The Group supplies high quality drugs and products and itrespects the issues through ten objectives, relative capitals and the key performance indicators ("KPI")[55].

---

[52] "*ASPEN'S ENCOURAGING EMERGING MARKET GROWTH*", ShauneenBeukes, March 8, 2019.

[53] Lactalis is a multinationalcorporation, owned by the Besnier family and based in Laval, Mayenne, France.

[54]Retrieved from: [http://www.aspen-reports.co.za/results/aspen-results-2019/commentary.php].

In 2019, the Group celebrates its 20th anniversary as a JSE[56](Johannesburg Securities Exchange) listed company.

2.2.1. The parties of the proceeding

In order to get portray a clear overview of the events, the Parties who took part in the preliminary investigation have been described.

The indicted is the Aspen group, a subsidiary of the South African company. On the other side, there are Altroconsumo, an Italian non-profit consumer association, and AIFA. The latter is responsible to supervise the price regulation of medicines in Italy and it operates autonomously, transparently and economically, as explained in the previous chapter.

In addition, among the parties participating in the ruling, there is GlaxoSmithKline (GSK), a British global healthcare company, since Aspen had acquired their medicine packagein 2009. The drugs previously distributed by the English pharmaceutical company are those that haverecorded a price increase.

The parties have been considered relevant for several perspectives: firstly, they provided a necessary evidencethat questions the conduct of Aspen group; secondly, they provided ample and continuous support for preliminary investigations.

[55]Retrieved from: [https://www.aspenpharma.com/sustainability-overview/].

[56] Johannesburg Stock Exchange wasfounded in 1887 and itis the mainfinancial centre of the AfricanContinent.

In fact, AIFA's participation in the proceeding with the Italian Antitrust Authority, AGCM, contributed to the conviction of abuse of dominant position by the Aspen Group, as will highlight in the following paragraph.

2.2.2. Aspen group

The defendant, Aspen Group, is formed by several holdings: APTL; AGI; AI; APIL and APHL, which we have been analysed in this paragraph.

Firstly, Aspen Pharmacare Holdings Limited (APHL) is the corporate responsible for defining pricing strategies for Aspen products in Europe.

Aspen Pharma Trading Limited (APTL), Dublin-based corporate, is the leader in the production and distribution of generic medicines and a distributor of branded medicines. It entered the European market, afterwards a worldwide transaction for the acquisition of the GSK(GlaxoSmithKline)[57] group of marketing rights for a package of anticancer drugs, as known as Cosmos[58]. In particular, APTL has the ownership of marketing authorisations for European markets.

However, the agreement with the English pharmaceutical companyofficially was produced by Aspen Global Incorporated (AGI). The latter controls Aspen Italia

[57] GSK is a British global healthcare company thatprovideshealth benefits to patients and consumers on some of the world'sbiggesthealthcarechallenges. Itproduces Cosmos drugs.
[58] Cosmos drugs are Alkeran, Leukeran, Purinethol and Tioguanina.

S.r.l. (AI), who conducts the role of broker on behalf of Aspen Pharma Ireland Limited (APIL) for Aspen products, sold using the "*consignment model*[59]".

The company "*Laboratorio Farmocologico Milanese*" (LFM) is the only dealer of Aspen products in Italy. Lastly, APIL is a company governed by Irish law, controlled by Aspen Pharmacare Holdings Limited (APHL) and it has the task of supplying chain management in Europe.

2.3. THE PROCEEDING

The preliminary activity began as a result of news concerning the significant price increases recorded in 2014 for some anticancer drugs marketed in Italy by the company Aspen Pharma Trading Limited, APTL and Aspen Italia S.r.l., AI.

However, Competent Drug Agency, AIFA, and Aspenstarted to discuss since 2013, when the Group requested significant price increase for Cosmos drugs.

In that situation, AIFA had to grant Aspen to increase prices, which, compared to the initials ones, had a raising from 275% to 1540%, as summarized in the table below:

[59] Consignment inventory model is a supply chain model in which a product is sold by a retailer, but ownership is retained by the supplier until the product has been sold.

TABLE 1: Old and new Aspen drug prices

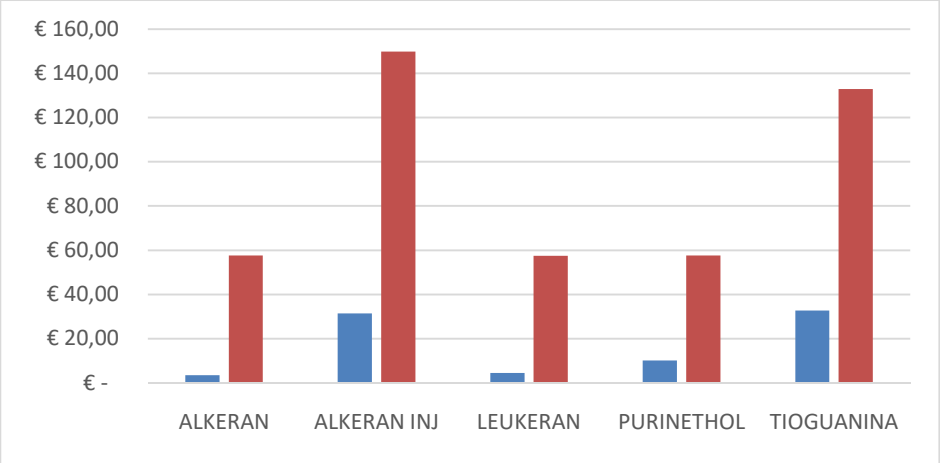
	OLD PRICE EX FACTORY*	NEW PRICE EX FACTORY	OLD PRICE TO CONSUMER	NEW PRICE TO CONSUMER	▵%P TO CONSUMERS
ALKERAN	€3,51	€57,62	€5,80	€95,10	1540%
ALKERAN INJ	€31,46	€149,87	€69,21	€247,35	257%
LEUKERAN	€4,54	€57,53	€7,50	€94,95	1166%
PURINETHOL	€10,19	€57,62	€16,82	€95,10	465%
TIOGUANINA	€32,72	€132,96	€53,99	€219,44	306%

**The ex factory price is the price of the drug corresponding to the industry's revenue before adding the percentages due for pharmaceutical distribution. On the contrary, the retail price is obtained by adding the percentages of remuneration of the subjects of the distribution chain (wholesalers and pharmacists) to the ex factory price.*

[Source: AIFA, on AGCM, 2016, page 3]

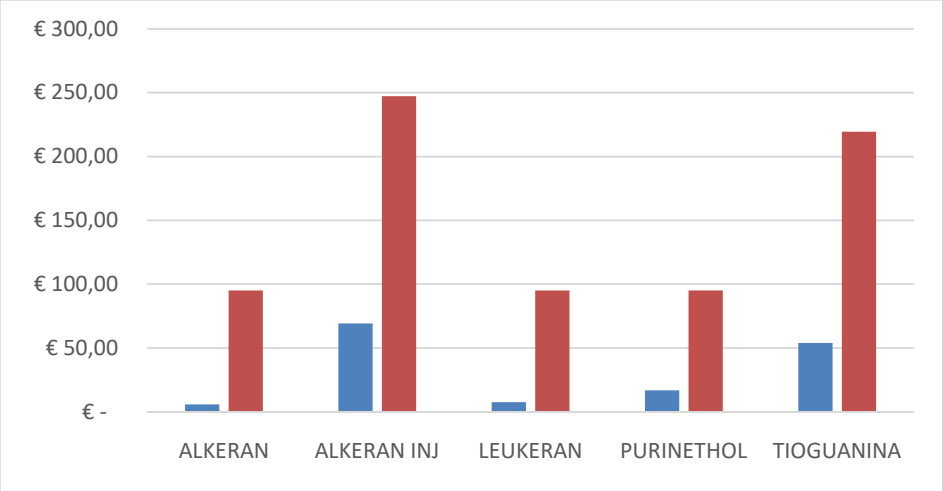
Nonetheless, the following graphs emphasise the evidence of price increases for each block of Cosmos drugs: The blue bar graph illustrates the former price; while the red one indicates those required by the pharmaceutical company.

Figure1 PRICE EX FACTORY



[Source: our elaboration on AGCM, 2016, page 3]

Figure 2 PRICE TO CONSUMERS



[Source: our elaboration on AGCM, 2016, page 3]

Although AIFA formally had the right to challenge the prices requested by the marketing authorization holder of a drug,some particularities have been at the centre of the issue.

The multinational company, in orderto justify its request,underlined that it had not yet had a return on the investment related to the purchase of patents.

However, accordance with the regulatory procedure, the price of a drug could increase if it has these characteristics:the absence of therapeutic alternatives in the class; the documented increase in production costs, with particular reference to the cost of the raw material; and the documented increase in production costs due to the regulatory provisions on improving the quality and safety profile of the specific drug.

During the negotiation between AIFA and ASPEN, the Authority antitrust has not verified the sustainability of the claims introduced from the pharmaceutical company. The reason for the lack of inspection was a constant threat from the Aspen Group to reduce the amount of drug distribution and possible withdrawal of products from the Italian market

Moreover, if AIFA had refused the requested increases, based on the rules in force, it would have had to exclude the products from *classes A* and *H*[60] to insert them in *class C*, which would have meant the possibility for the company to freely

[60]Those medicines were included in the refund categories "A" and "H"
(in charge of the SSN, the Italian Sanitary National System).

define the prices, but at the same time the debiting of the relative amounts to the full charge of the patients.

Obviously, these eventualities wanted to be avoided by AIFA and by consequence Aspen request has been recognised.

As a result, on 10 September 2014 Altroconsumo reported to the Ministry of Health and AIFA the results of the withdrawal of complaints with which its members informed the association of the disappearance from the market of a series of drugs, including those object of the proceeding.

In the report, the association noted that the disappearance of many drugs from the distribution circuit has led to very significant increases in the price of medicines in Italy.

However, already in July 2014 the Antitrust Authority was aware of the increase in the prices of Aspen drugs and following the preliminary investigation phase, in which all the data relating to the AIFA and Altroconsumo survey have been collected.

On November 19, 2014, the Authority has launched a preliminary investigation.

This has occurred pursuant to art. 102 of the TFEU and of the article 14 of the law no. 287/1990 towards APTL and AI, in order to verify the existence of restrictive behaviour by the aforementioned companies.

Specifically, the article 102 of the TFEU[61] cites: "*Any abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it shall be prohibited as incompatible with the internal market in so far as it may affect trade between Member States.Such abuse may, in particular, consist in: (a)directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;(b)limiting production, markets or technical development to the prejudice of consumers; (c)applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage; (d)making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts*".The *point (a)* is relevant in the proceeding against the pharmaceutical company.

Concerning to article 14 of law n. 287/1990[62] the Authority: " *in case of alleged violation of articles 2 or 3, notifies the opening of the preliminary investigation to the companies and entities concerned; it may at any time during the investigation asks to the companies, organizations or persons in possession of information, that produce documents useful for the purpose of the preliminary*

[61]Retrieved from: https://eurlex.europa.eu/legalcontent/EN/TXT/HTML/?uri=CELEX:12008E102&from=EN]

[62]Retrieved from: [https://www.agcm.it/chi-siamo/normativa/legge-10-ottobre-1990-n-287-norme-per-la-tutela-della-concorrenza-e-del-mercato]

investigation,such as news, information or data relating to the companies.[…] Officials of the Authority in the exercise of their functions are administrative administrators. They are bound by professional secrecy".

Subsequently, inspections were carried out for other parts of the Group, following the summary of the following table:

TABLE .2 PARTICIPATION OF ORGANIZATIONS

DATE	Contributing subject	Object of contribution
27th November 2014	Altroconsumo	AI
27th November 2014	Competition and Consumer Protection Commission[63]	APTL
27th November 2014	Competition and Consumer Protection Commission	APIL
27th November 2014	AIFA	LFM
27th November 2014	AIFA	GSK

[Source: our elaboration on AGCM 2016 gathering of 29th September 2016, p.4]

[63]Competition and Consumer Protection Commission(CCPC) is an Irish state agency established in 2014, combining the previous functions of the Competition Authority and the National Consumer Agency.Retrieve from: [https://whatsnew.citizensinformation.ie/2014/11/07/the-competition-and-consumer-protection-commission/]

On December 9, 2014, Altroconsumo submitted an application for participation in the preliminary investigation procedure and in 2015 the Authority extended the investigation to the Irish company APIL and the South African parent company APHL. The GIMEMA[64] Foundation, in addition to the interested parties, took part in the ruling.

During the proceeding, the Authorityhas requested for information to AIFA, to the Ministry of Health and to Aspen, which presented briefs on 20 July 2015.

On October 30, 2015, the notice of preliminary Inquiries was notified to the Parties, following the Authority's resolution of October 28, 2015.

The deadline for the conclusion of the proceeding was postpone to March 20, 2016. Aspen has filed a final defenceon February 2, 2016, while Altroconsumo has produced a final testimony on February 3, 2016.

In addition, on February, the hearing of the Parties has been held and the new final deadline for the proceedings has been set on 30 June 2016.

At the assembly, the Authority requested to*Agribusiness and Transportation Department*to proceed with the clarification of the disputes brought against the Party with reference to the possible commission of an abuse of a dominant position in violation of Article 102, “point a” of the TFEU.

[64]The Italian Group for adult hematologic diseases (GIMEMA) is a private non-profit organization established in 1982, with the aim of coordinating clinical research activities and establishing diagnostic and therapeutic protocols in the field of acute leukemias.

On April 22, 2016 a new notice of preliminary Inquiries was notified following the Authority's resolution of April 19, 2016 and the end of the proceedings was again extended to September 30, 2016.

The Parties were heard in the final hearing before the Board on July 5, 2016[65].

2.3.1. Costs, prices and estimates of unfairness

In the various economic sectors, a "fair" price has been difficult to define, sincethere are often typical difficulties, such as to recognise the economic components of product costs. The reason these problems exist is the presence of many traceable variables in the definition of costs held by a company, such as research and development activities.

Regarding the R&D costs of a medicine, the estimate is attributable to the Tufts Centre[66] for the study of Drug Development, according to whichnowadays the average amount of a drug would have exceeded 2.5 billion dollars.

Nevertheless, this estimate has been subject to many criticisms both for the questionability of some cost items and for confidential data provided by the pharmaceutical company, that cannot be verified by third parties.

[65]Ruling no. 26185 of 29 September 2016, provision A480- "*Aspen / Increase in drugprices.*

[66]Itprovidedscholarlyassessments of the time, cost, and risk of new drugdevelopment, and ithaveconsistentlyadvocated on behalf of initiativesthatfurther the cause of pharmaceuticalinnovation.

Specifically, with regard to the Aspen case study, it was hard to ascertain the data and relative estimates since some peculiarities of the drugs and the companies have been involved.

The same Cosmos drugs have been developed for a long time, even before they have been acquired by the Aspen Group. Therefore, the request of increase in priceto recover the relative R&D costs has been considered ambiguous, considering that those have already been amortized time ago.

In addition, the Aspen Group has always been active uniquely in the production and marketing of equivalent drugs, so it hasnot had to face any risks of failure to search for new products, the so-called "*dry holes"*[67].

The principles developed by the EU Court of Justice , in the analysis of antitrust, concerning the structure of costs and prices, the principles developed by the EU Court of Justice, are included in an investigation known as "Test United Brands[68]".

In the Aspen case, the AGCM proceeded to determine the economic value of the performance of the company for verifying whether there was a disproportion among the costs actually incurred for the production of the drugs and the new prices requested from AIFA, so as to ascertain their inequity.

---

[67] A dry holeis a business venture thatends up being a loss. The "dry hole" wasoriginallyused in oilexploration to describe a wellwhere no significantreserves of oilwerefound. Thistermisnowoftenused to describeanyfruitless commercial initiative.

[68] The United Brands test determinestwoconditions for excessivepricing: the "*differencebetween the costsactuallyincurred and the priceactuallychargedisexcessive*" and a "*pricehasbeenimposedwhichiseitherunfair in itself or whencompared to competingproducts*".

As already reiterated several times, the case was peculiar because the determination of the judgment on the economic value has margins of discretion. In fact, in the provision of the AGCM it is emphasized that "*there are no quantitative thresholds or precise arithmetic relationships that define what measure the disproportion between prices and costs must assume to be considered indicative of an abuse of exploitation*".

Furthermore, since Cosmos drugs are "*life-saving*" medicines and without therapeutic alternatives, consumer's willingness to pay has not been considered a possible solution.

For these reasons, the AGCM's analysis has been made according to two methods of assessing the disproportion between prices and costs: the first focuses on the profits of the company by each of the Cosmos drugs, in terms of gross contribution margin, i.e. the difference between the sale price of a product unit and all related variable costs; and the second, instead, it is aimed at analysing the differences between the revenues of Aspen and a parameter called "*Cost Plus*[69]".

However, regarding the percentage of surplus revenue, AGCM had not a specific one that would determine the disproportion, through other jurisprudential cases, so it determined that a percentage of 25% was already excessive.

[69] The "*Cost Plus*" parameteris made up of the sum of directcosts, a share of indirectcosts and a measure of profitabilityunderstoodas a reasonableremuneration and reasonable production recognizes the company.

To conclude, all the elements analysed led the AGCM to consider unfair the new prices requested by Aspen, since they are the result of a distorted and instrumental exercise of the right to negotiation provided for by the national law[70].

Regarding the pharmaceutical sector, the WHO has formulated a reference definition, stating that "*a fair price is that accessible to health systems and patients and at the same time provides sufficient market incentives for the industry to invest in innovation and in the production of medicines*". Despite the difficulties it has been possible to obtain a resolution by Italy on price transparency.

Giulia Grillo, the Former Minister of Health of the Italian Republic, said that there are new standards for transparency that will help every country negotiate drug prices.

In addition, the Minister emphasized "*Until now, questioning the price criteria of medicines has been a taboo, but now something has changed. The WHO decision opens a new path in drug price negotiations, setting a principle of transparency from which we do not go back. Negotiating on the basis of more complete information will lead to better dialogue with the industry, to have a more*

[70] "*La cura della concorrenza*", L. Arnaudo, G. Pitruzzella. 2019, pp. 123-126.

competitive and innovative market and therefore to buy more health for the same resources[71]*"*. This aspect will be covered in the third chapter.

2.3.2. Aspen case in the new frontiers of price abuse

Regarding the developments of the case: after AGCM considered the unfairness of prices,despite these having been formally authorized by AIFA, a new preliminary investigation has been prepared to verify the potential non-fulfilment of the warning contained in the ruling.

The decision signed the importance of the regulatory plans and the antitrust interventions. The Authority must guarantee a definition of prices that allow effective access to medicines, while taking profits into account.

Specifically, the regulation consists of specific and preventive interventions, aimed to determine the marketing and the reimbursement by the SSN of a drug.

Regarding the antitrust interventions, it considers a suspicious situation, that will be assessed from a judicial point of view, in particular if there is an unlawful phenomenon.

The develop of a new regulation is directed towards the products,as known as "innovative", since they have been affected by R&D.

[71] "*Farmaci: l'Oms adotta la risoluzione dell'Italia sulla trasparenza dei prezzi",* Ernesto Diffidenti, May 2019. See [https://www.sanita24.ilsole24ore.com/art/dal-governo/2019-05-28/farmaci-oms-adotta-risoluzione-italia-trasparenza-prezzi-145755.php?uuid=ACTRKmJ&refresh_ce=1]

A new drug,that enters the market, has allowed a significant contribution in terms of innovation. However, in the pharmaceutical market, companies are forced to inform the regulatory agencies because in the case of new drugs aimed at treating rare diseases, prices can even reach more than half a million euros. Consequently, in order to avoid situations of abuse of dominant positions, introducing more urgent rules on price transparency has been considered relevant.

A further situation examined is that of the "public utilities", such as the distribution of water, electricity, gas and transport, which are considered to be highly innovative in terms of monopolistic tendencies. This is a clear starting point for reflection to hypothesize to do so also for essential drugs, an idea already expressed by Estes Kafauver (Committee on the Judiciary, subcommittee on Antitrust and Monopoly)[72].

In fact, in the Italian national law, as stated in the art. 29, paragraph 1, of the law number 833/1978[73], the institutive law of the SSN expressly refers to the "*social function of the drug*" and "*prevalent public purpose*" of the relative production.

To conclude, these reflections are useful for improving regulatory and antitrust activities in the future, so as to have a clear scenario to determine new frontiers to overcome price violations[74].

[72]Between 1957 and 1963, a Senatecommissionchaired by Democratic Senator EstesKefauverheld a long series of hearingsaimedatinvestigating the issues of administrativeprices, industrial concentrations and the restivemonopolyeffects in various industrial sectors, including the pharmaceuticalsector.

[73]Retrieved from: [http://www.comune.jesi.an.it/MV/leggi/l833-78.htm]

2.3.3. Conclusion of the proceeding

On September 29, 2017 Aspen sent AIFA a first version of the review dossiers of the contractual conditions for Cosmos medicines. However the price proposals formulated by Aspen has not beenconsistent according to the requests: in fact, AIFA has accused the multinational of inactivity because it has not referred to the initial prices, but the financial value subsequently negotiated with the CPR[75], compared with the European weighted average price.

As a result, in November 2017 Aspen delivered a new version of the price review dossier, with two sections called A and B. Section A has been prepared in application of the AIFA Guide "*relating to the presentation of the classification and price application*", starting from the prices prior to the 2013/2014 negotiation. Nevertheless, Aspen stated that the application of these prices would result in positive gross margins for the Purinethol, Leukeran and injectable Alkeran drugs, while the margins for Alkeran tablets and Tioguanine have had a negative value.

In section B of the dossiers, Aspen proposed price increases based on the following reasons: the amortization of the cost incurred for the purchase of the trademarks from GSK for a period of ten years; investment costs and other similar costs incurred with third-party producers; the costs of regulatory nature and stock

[74] "*La cura della concorrenza*", L. Arnaudo, G. Pitruzzella. 2019, pp. 127-129.
[75] COMITATO PREZZO E RIMBORSI.

depreciation incurred or in any case capitalized by the group; the expenses relating to a structure set up in South Africa to guarantee the sustainable supply of the Cosmos; indirect costs; the additional discounts to be paid to the public administrations on Cosmos drugs as payback and for the pro-rata contribution to the breakthrough shelf of the pharmaceutical expenditure ceiling.

Aspen has emphasized its request because of the products had the characteristic of "orphan-like drug[76]", so that they should be recognized an operating profit margin of about 50%.

According to AIFA, the proposed prices have been considered inappropriate compared to the requests, and on 7 December 2017 Aspen stated that it had withdrawn section B of the price review files. However, the Group reinforced that with the application of these criteria, the sale of products had a loss with significant direct marketing costs, but especially they would not have been adequate for products with pharmacological characteristics such as those of the Cosmos package.

In addition, in the same communication, Aspen also noted that AIFA's request for explicit renunciation of section B "*implies a lack of understanding of the company's situation in relation to these drugs, based on a misinterpretation of the evaluations of the AGCM*".

[76] An orphan-likedrugis a drugintended for the treatment of rare diseases and which, whererecognized by the competentmedicalauthorities, ithas the right to a legal regime of protection from competition

During the first preliminary investigation phase, the Antitrust Authority imposed a penalty of 5 million euros on the Aspen Group. However, on June 13, 2018 AGCM closed the proceedings against Aspen.

Following this measure, the prices of anticancer drugs have been reduced from a minimum of 29% to a maximum of 82%, as shown in the tables below:

TABLE 3 PRICES EX FACTORY OF COSMOS DRUGS

	2013	2014	2018
ALKERAN	€ 3,17	€ 57,62	€ 11,66
ALKERAN INJ	€ 28,39	€ 149,87	€ 70,70
LEUKERAN	€ 30,76	€ 132,96	€ 94,76
PURINETHOL	€ 9,58	€ 57,62	€ 20,37
TIOGUANINA	€ 4,27	€ 57,53	€ 10,51

[Source: on AGCM,2018 gathering of 13th June 2018, p.23]

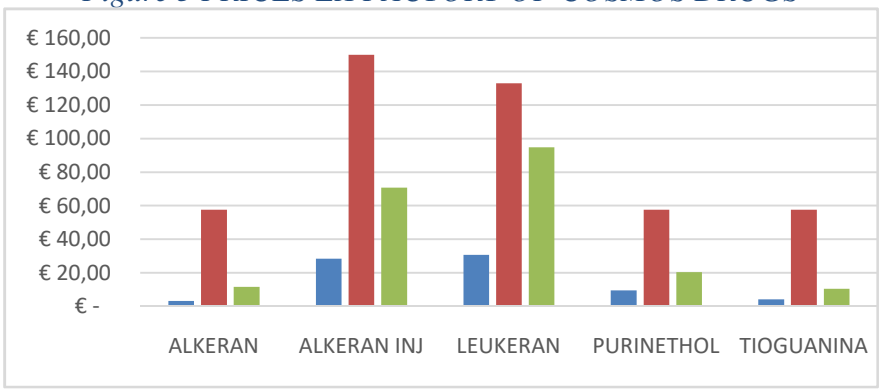
TABLE 4 RETAIL PRICES OF COSMOS DRUGS

	2013	2014	2018
ALKERAN	€ 5,80	€ 95,10	€ 19,24
ALKERAN INJ	€ 69,21	€ 247,35	€ 116,68
LEUKERAN	€ 53,99	€ 219,44	€ 156,39
PURINETHOL	€ 16,82	€ 95,10	€ 33,62
TIOGUANINA	€ 7,50	€ 94,95	€ 17,34

[Source: on AGCM, 2018 gathering of 13th June 2018, p.23]

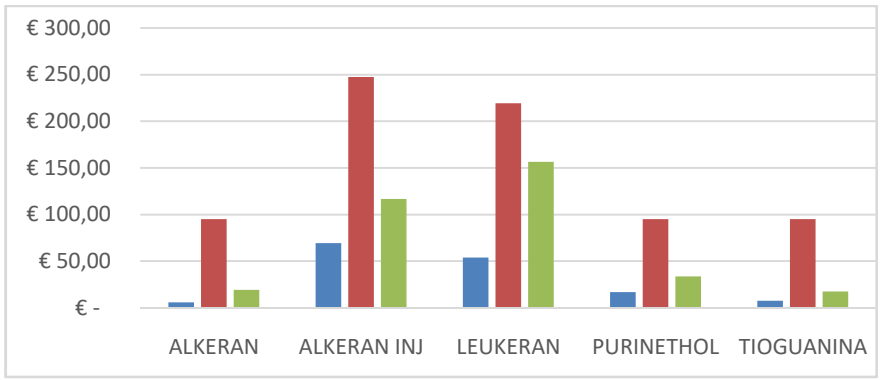
These prices were established following a financial agreement between the Aspen Group and AIFA on 18 April 2018 and the chart below shows how these prices have decreased:

Figure 3 PRICES EX FACTORY OF COSMOS DRUGS



[Source: our elaboration on AGCM, 2018 gathering of 13th June 2018, p.23]

Figure 4 RETAIL PRICES OF COSMOS DRUGS



[Source: our elaboration on AGCM, 2019 gathering of 13th June 2018, p.23]

The green bar graph illustrates the prices, following the agreement between Aspen and AIFA.

The application of the new prices has beeneffective even in the period prior to the date of its issue, hence the date on which the abusive nature of the old prices has been ascertained.

The Authority therefore decided to close the proceeding and determine Aspen Group's compliance with its decision. Furthermore, following the outcome of the new negotiations, AIFA also has been satisfied.

Finally, as stated on the provision: "*The abuse of exploitation of unfair prices lasts as long as the exploitation of the imposed prices remains* [Tar Lazio, sentence number 8945/2017 cit., Paragraph 10.6] *and that Aspen and AIFA on April 18 they reached an agreement under which the prices considered unfair by the Authority are no longer in force with retroactive effect starting from the ascertainment of the abuse of dominant position, which considers that Aspen has put in place every fulfilment aimed at the definition of prices not unfair*[77]".

[77]Ruling no. 27209 of 13 June 2018, provision A480B- "I*ncrease in drugprice Aspen-Non-compliance"*.

2.4. LEGISLATIVE AND REGULATORY SITUATION

During the analysis of the case, classification of medicines for human use based on their reimbursement scheme has been relevant.

In fact, this classification distinguishes medicinal products on the market based on the object that bears the relative expense.

Furthermore, the Aspen Grouphas endangered to change the class of reimbursement of its drugs: from *class A* and *H* to *class C*. For this reason,so as to have a clear picture with article 8, clauses 10 and 14 of the. 537/1993, the following classes of refund are defined:

TABLE 5 CLASSES OF REDEEMABILITY

BANDS	REDEEMABILITY
Class A	Essential drugs for chronic diseases entirely covered by SSN
Class H	Hospital usage drugs entirely covered by SSN
Class C	Drugs entirely covered by patient. These are divided into drugs with the obligation of medical prescription and drugs without the obligation of medical prescription. Class c drugs prices are freely decided by manufacturers and AIFA can manage the value and cost of these.

[Source: our elaboration on the description of the classes of redeemability, on AGCM,2016 gathering of 29th September 2016, p.8]

2.4.1. Relevant market of Aspen Case

From a pharmaceutical point of view, in order to define the relevant market in which the Aspen Group operates, the therapeutic class of medicines, namely the chemical action and the therapeutic purpose, has been considered.

These classes have been identified using the anatomical therapeutic chemical classification system, which shows 5 different hierarchical levels.

At the third level ATC ("ATC3") pharmaceutical products are grouped according to their therapeutic indication, or the intended use. This level is generally used as a starting point for defining relevant product markets in competitive cases and it includes products that can be considered substitutes.

The Antitrust Authority mainly refers to the economic-behavioural analysis and in this case it cannot exclude preliminary medical studies on the possible therapeutic substitution.

Aspen products are anti-cancer products (antineoplastic agents) used during certain stages of leukaemia therapy, lymphoma, myeloma, etc.

Each medical specialty is composed of a different active ingredient (ATC5 level), as shown in the following table:

TAB 6 ACTIVE PRINCIPLE LEVELS

	II ATC LEVEL	III ATC LEVEL	ACTIVE PRINCIPLE V ATC LEVEL
ALKERAN	Antineoplastic agents (L01)	Alkylating agents (L01A)	**MELFALAN**
LEUKERAN	Antineoplastic agents (L01)	Alkylating agents (L01A)	**CHLORAMBUCIL**
PURINETHOL	Antineoplastic agents (L01)	Antimetabolites (LO1B)	**MERCAPTOPURINE**
TIOGUANINA	Antineoplastic agents (L01)	Antimetabolites (LO1B)	**THIOGUANINE**

[Source: Our elaboration on principle levels of medical specialty, on AGCM,2016 gathering of 29th September 2016, pp.16-17]

No other products on the market have the same molecule: this is the reason why Aspen medicines has not been replaced directly.

On the demand side, there are many factors that distinguish Cosmos products from hospital alternative ones.

The main features that make Aspen a monopolist in its relevant market:

• *High tolerability*: they are well tested and are characterized by a low level of toxicity and no side effects;

• *Domestic use*: they are appropriate for domestic therapies and consist mainly of pills, unlike products that require hospitalization, such as cardiovascular transfusions;

• *Rigidity of demand*: due to therapeutic continuity, which makes demand inelastic despite the presence of alternatives.

National and international experts have established the Aspen products irreplaceable. Even GSK, the former holder of the drugs examined, states that Cosmos drugs are without therapeutic alternatives for those cancer patients who suffer from critical illnesses.

Therefore, the absence of therapeutic substitutability between the medicinal products considered and other products encloses the relevant market at the level of a single active principle (ATC5).

In every market, Aspen products are exclusives, so that it is monopolist in its relevant markets.[78]

2.4.2 International background: how the international Antitrust Authorities operate

In this chapter some examples of other pharmaceutical companies have been reported, the purposeis to highlighthow the Antitrust Authority acts in the international background.

In 2016[79], the US pharmaceutical company Pfizer and the distributor Flynn Pharma have been fined almost 90 million pounds ($114.6 million) for increasing

[78]Ruling no. 26185 of 29 September 2016, provision A480- "*Aspen / Increase in drugprices,* pp. 16-17.

[79]Competition and Markets Authority, proc. CE/9742-13, "*Pfizer/ FlynnPharma",* decisione del 7 dicembre 2016.

the cost of a drug that treating epilepsy up to 2,600% by the Authority of Competition and Market in the United Kingdom, since it had considered the fixed price "*excessive and unfair*".

The Competition and Market Authority (CMA) noted that companies have violated competition law by charging "*unfair and excessive prices*" for the drug, which is used by 48,000 people in the UK.

Specifically, Pfizer has been sanctioned with 84.2 million pounds ($106 million) and Flynn Pharma with 5.2 million pounds ($ 6.4 million). In addition, the Authority had also imposed to the price of the drug a lower value.

The preliminary investigation began because the Authority has found out that in 2012 the two companies changed the name of a drug, formerly known as "*Epanutin"*, in order to deliberately increase the price. In this way, the UK National Health Service paid 2 million pounds a year in 2012 ($ 2.52 million) and about 50 million pounds ($ 62.92 million) in the year 2013.

Philip Marsden[80] has been charged of the case, and he stated that "*even if they have the freedom to set prices, companies that have a dominant position in the market should not abuse this situation and set excessive and unfair prices*".

In addition, Marsden declaredthat fine imposedwas the highest on the pharmaceutical industry by the Agency so far, and he affirmed: "*in this case there*

[80] Dr. Philip Marsdenis a Senior Adviser in CRA'sCompetitionPractice.

is no justification for the price increase, because these capsules are a drug very old for which there have been no recent significant innovations or investments"[81].

Nevertheless, on 7 June 2018[82] the Competition Appeal Tribunal (CAT) of the United Kingdom has pronounced the mistrial for the pharmaceutical companies Pfizer and Flynn. The British Court, while supporting the validity of the decision of the CMA in the part in which the two companies hold a dominant position in the relevant market, they have held that the Authority of Competitionhad erred in stating that the companies in question had violated Article 102 TFEU.

In particular, the CAT considered that the CMA had erroneously restricted the determination of the excessive price without establishing whether there was a disproportion between the price actually imposed by the dominant company and the price that the company would hypothetically practice in a competitive market (*reference price*)[83].

A further similar case occurred on 31 January 2018 and it concerns the pharmaceutical distributor CD Pharma[84].

---

[81] *Federazione delle Associazioni degli Informatori Scientifici del Farmaco e del Parafarmaco,* December 8th, 2016[https://www.fedaiisf.it/gran-bretagna-super-multa-pfizer-aver-aumentato-prezzo-un-farmaco-del-2600/]

[82]Competition Appeal Tribunal, case 1275-1276/1/12/17, "*Pfizer e FlynnPharma contro Competition and Markets Authority",* sentenza del 7 giugno 2018.

[83] "*Prezzi eccessivi ed iniqui nel settore farmaceutico. Il CAT britannico annulla la decisione della CMA nel caso Pfizer e Flynn",* Roberto A.; Jacchia Davide Scavuzzo, 2018. Retrieve from: [https://www.dejalex.com/wp-content/uploads/2018/09/1.-Prezzi-eccessivi.pdf].

[84] CD PharmaSrlwascreated in 2009 to operate in the pharmaceuticalindustry and thenexpanded to Uppsala, Sweden.

The Danish Competition Council ("DCC") has pronounced for abuse of dominant case by charging unfair prices for the drug Syntocinon, produced by CD Pharma. Syntocinon contains oxytocin, which is an active ingredient given to pregnant women in connection with childbirth.

During the preliminary inquiry, since 28 April 2014 to 27 October 2014 CD Pharma have increased the price of Syntocinon from 45 DKK (6 euros) to 945 DKK (127 euros), thus with a price increase of 2000%.

CD Pharma therefore have exploited their dominant position,through an exclusive distribution agreement with the product manufacturer.

For this reason,Amgros[85], a wholesale buyer for hospitals, have paid an unfair price on the Syntocinon drug, for almost six million DKK (about 780,000 euros).

However, CD Pharma has not been capable to explain the price increase, for istance with higher costs or costs for research and development. Consequently, the DCC has ordered CD Pharma to refrain from such offensive behavior in the future.

As a result, Amgros referred for a period to the CD Pharma competition, Orifarm[86], which however could not guarantee enough coverage for the

[85]Amgrossecures the supply of drugs and hearing aids to public hospitals and hearing clinics. See [https://amgros.dk/en/about-amgros/]

[86]ORIFARM, ABOUT US [The Orifarm Group is a progressive European player in the healthcare business].

Syntocinon drug. For this reason, the buyer has not forced to relate with CD Pharma again, due to the exclusive distribution agreement[87].

In summary, the Council considered that the price charged by CD Pharma for Syntocinon after the price increase has been unfair. The case examined has been submitted to the prosecutor fro serious economic and international crimes[88].

2.4.3. Access to medicines for creating welfare

During the analysis of the Aspen case and the other similar cases, human rights, affected by many decisions regarding regulation and antitrust ruling, have always been considered fundamental.

According to Eleanor Fox, an esteemed antitrust scholar, democracy is necessary both for the expression of important economic rights, such as the freedom to conduct a business, and for fundamental rights, which can be traced back to the highest regulatory levels of the laws in force (E. Fox, 2017).

In fact, article 2 of the Italian Constitution of 1947 recognizes and guarantees the "*inviolable rights of the persons*" and the main international acts, such as the "*Universal Declaration of Human Rights*" adopted by the United Nations in 1948,

[87] DANISH COMPETITION AND CONSUMER AUTHORITY, *"CD Pharmahasabuseditsdominant position by increasingtheirprice by 2,000percent",*2018. See[https://www.en.kfst.dk/nyheder/kfst/english/decisions/2018-cd-pharma-has-abused-its-dominant-position-by-increasing-their-price-by-2-000-percent/]

[88]Retrieved from: [https://en.kromannreumert.com/News/2018/02/Danish-Competition-Council-finds-Pharmas-200-price-increase-unfair]

the "*European Convention of Human Rights*" signed in 1950 and the "*Charter of Fundamental Rights*" adopted by the EU in 2000, ensure the right to life.

However, the constituent principles, despite the recognition of the right to life, are sometimes "superficial" and "obvious" in the explanation.

For this reason, a more "concrete" aspect of the right to health has been introduced: article 25, paragraph 1 of the *Universal Declaration*, which emphasizes that every individual has the right "*to the necessary medical care and social services*" or article 32 of the Italian Constitution which cites "*The Republic protects health as a fundamental right of the individual and as a collective interest, and guarantees free medical care to the indigen*t".

In addition, the "*International Convention on Economic, Social and Cultural Rights*", provided by the relevant Committee in 2000, has force the Contracting States to guarantee the right of everyone to enjoy the highest standard obtainable of physical and mental health.

To conclude, this is a legal debate focused on human rights with the aim of creating an economic correspondence, governed by notions of public utility, to ensure that a welfare project is increasingly developed.[89]

[89] "*La cura della concorrenza*", L. Arnaudo, G. Pitruzzella. 2019, pp. 145-148.

3 CHAPTER: ECONOMIC ANALYSIS

3.1. INTRODUCTION

In the third and final chapter, the aspect of economic analysis has been highlghted.

Firstly, the drug policies have been deepened: from the manual for understanding the policies to the pharmaceutical governace. In addition, it has been reported the news that Italian proposal for transparency on drug prices has been recently approved in Geneva.

It is also noteworthy to study the regulation of markets, aimed at the background of the Aspen case. Indeed, the competitive market, in which the Aspen Group operates, has been illustrated through an articulated analysis of issues such as: conflicts of interest, asymmetric and monopoly information.

Finally, the specific analysis of the case data has studied, in particular focusing on: the price analysis methodology, carried out by AGCM during the proceeding,and theprice decisions.

This economic analysis is required from an economic and behavioural standpoint, considering also the reasons which led Antitrust Authority to take action.

3.2. POLICY OF MEDICAL PRODUCTS

Policy of medical product has been developed for various reasons.

First of all, State bodies have the obligation to provide security for citizens over the entire national territory,as stated in the Italia Constitution: "*The State has exclusive legislation in the following matters*: *[..] determination of the essential levels of the services concerning the civil and social rights that must be guaranteed throughout the national territory"* (article 117, paragraph 2, letter m of the Constitution).

Considering the different instances that have occurred regarding the supply of drugs, Authorities haveintervened,with effective regulatory instruments, so that safety could be guaranteed for the consumer and a strategic economic framework could befavoredaccording to law[90].

To confirm this panorama, it has been introduced the Italian magazine,that adheres to the International Society of Drug Bulletin (ISDB), an international association that brings together independent sources of information on medicines.

More specifically, ISDB was founded in 1986, with the support of the WHO Regional Office for Europe.

[90] "La politica del farmaco: Quadro normativo, problemi, proposte", Fondazioni Astrid e Magna Carta, 2014. [http://www.quotidianosanita.it/allegati/allegato7779097.pdf]

The general objective of the association is to encourage and assist the development of independent drug bulletins in all countries, in order to facilitate cooperation between them.

To address public health and drug information issues, ISDB has developed connections with many relevant organizations and members involved in various activities and campaigns. The main objectives are: access to information on medicines and the impact of the promotion of the pharmaceutical industry.

The association's activities also include the exchange of information on new drugs,the adverse effects and drug promotion and regulation[91].

In detail, "*Policy on Medical Product*" (in italian "*Politiche del Farmaco*") is the creation of a web space for the discussion of drug policies, in which can be found summaries of published contributions or ISDB journals.

The aim of the project is to publishall the proposal, initiative, decision that has a relevance in the sector of medicines. Among the useful information, there are: the research procedures to drug registration methods; the assessment of innovation and therapy to the definition of prices; the activity of Italian and European regulatory agencies (AIFA and EMA); the role of local and regional pharmaceutical services, from interventions aimed at modifying the prescriptive practice of the individual clinician to those that change the access modalities of the population.

[91]About the International Society of DrugBulletins (ISDB) [https://www.isdbweb.org/what-is-isdb]

This purpose has been origineted from the thought that a public discussion may be useful on topics that have an impact on citizens, operators, decision makers and companies. In addition, the idea to promote transparency has been relevant in order to make people involved less lonely.

Indeed, this space for reflection is a useful tool for making explicit the decision taken, in order to mitigateany form of unlawful, which can influence behavior[92].

3.2.1. Medicinal products: Manual Policy

Over the years, there have been many economists and researchers who have taken an active part in discussions of these issues.

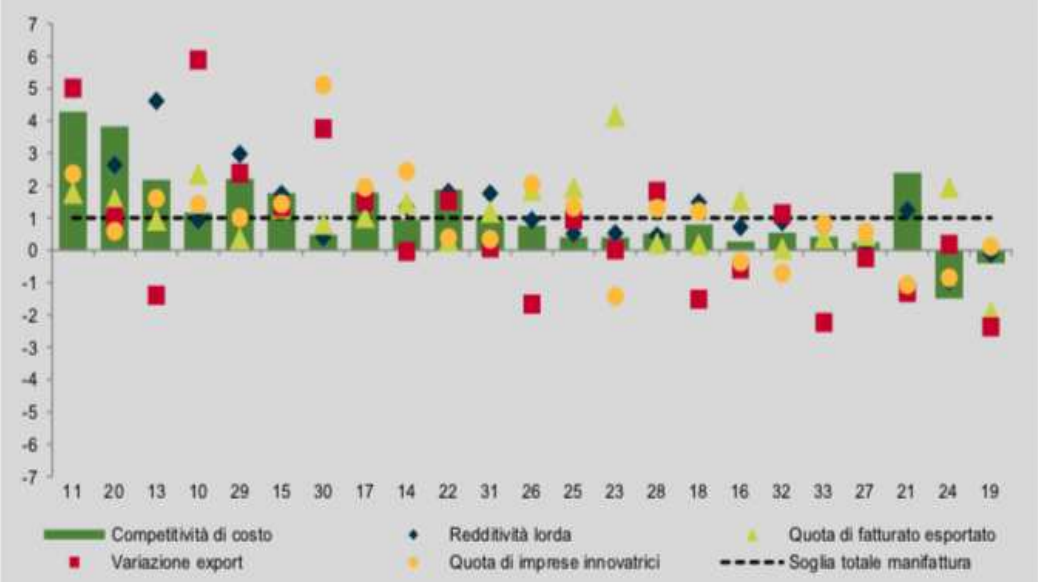
In fact, there are several literatures concerning the regulatory decisions and definition of drug prices, such as the volume "Drug Law", by Giuseppe Franco Ferrari and FaustoMassimino (Bari, Cacucci, 2015)[93].

The two authors put the spotlight on the importance of the sector, not only from an economic-financial point of view, but also on a study of the interweaving of policies and normative rules that involve multiple institutional levels.

According to this, in Italy the pharmaceutical sector (green histograms no. 21) has a significant importance in terms of cost competitiveness, as shown by the graph below:

[92] ABOUT *"Politiche del Farmaco"* [https://politichedelfarmaco.it/cosa-e-politiche-del-farmaco/].
[93] "*DIRITTO DEL FARMACO, medicinali, diritto alla salute, politiche sanitarie",* Giuseppe Franco Ferrari and Fausto Massimino, 2015
[https://www.academia.edu/13443580/Diritto_del_farmaco__Indice_e_introduzione]

Figure 5COMPONENTS OF THE STRUCTURAL ISCo BY SECTOR OF ECONOMIC ACTIVITY (2008-2016 percentage changes offset by the average changes in total manufacturing)[94]



[Source: ISTAT data, Report on the competitiveness of the production sectors, 2019, page 48]

The aim in the reporthas to elaborate a description as complete as possible of the drug law. Starting from the phase of research and experimentation to that of authorization to produce. Subsequently,it has focusedon the production, the distribution, the acquisition of the National Health Service.Finally, it has to concentrated on the consumption, with particular focus on medicines reimbursed by the SSN and incidental references on products to be paid by patients.

[94] REPORT ON THE COMPETITIVENESS OF THE PRODUCTION SECTORS, 2019, page 48 [https://www.istat.it/storage/settori-produttivi/2019/Rapporto-Competitivita-2019.pdf].

To conclude, the manual has highlighted the difficult characteristics of the pharmaceutical market and its different aspects compared to other commodity sectors, focusing on all aspects that allow the understanding the policies of medical products[95].

3.2.2. Pharmaceutical governance

In June 2018, the Conference of Regions and Autonomous Provinces has presented new proposals for the elaboration of a new governance of the drug to the Minister of Health.

The main objective is always to considered medicines as an essential tool for health protection. It should be remembered that drugs have been supplied by the National Health Service and in accordance to this,a collection of risk-benefit information has tobe guaranteed to citizens.

In order to develop the new proposals, the role of the Italian Medicines Agency (AIFA) is relevant, since it ensures compliance with the financial framework programmed for the pharmaceutical sector. In fact, the price of drugs has a significant role, as can be seen in the extract from the document:" *AIFA adheres to the principle that therapeutically equivalent drugs must have the same reimbursement price charged to the SSN; higher prices charged to the SSN can be*

[95] "*Il manuale per capire la politica del farmaco*", *Sanità24*, Renato Balduzzi, 2016. [https://www.sanita24.ilsole24ore.com/art/lavoro-e-professione/2016-03-31/il-manuale-capire-politica-farmaco-115314.php?uuid=ACGKtixC&refresh_ce=1]

recognized only against an added therapeutic value for patients, and must be commensurate with the added value".

In emphasize its role, the Agency guarantee "*a relationship of collaboration with the Regions, a transparent dialogue in institutional relations, efficiency in the management of bureaucratic burden, facilitation of clinical research and collaboration in the application of the principle of free competition*"[96].

In December 2018, the ministerial document on the subject of Pharmaceutical Governance was published.

The planning document for the new Pharmaceutical Governance was presented by the Former Minister of Health, Giulia Grillo, with the collaboration of the president and founder of the "Mario Negri" Institute for Pharmacological Research, Silvio Garattini; the director of the AIFA, Luca Li Bassi; and to the coordinator of the table of Regions on Pharmaceuticals (as well as president of the CPR-AIFA commission), Francesca Tosolini.

The new Pharmaceutical Governance includes the revision of the pharmaceutical handbook, the verification of the dispensation of personalized doses, the digitization of the AIFA registers, the new payback measures and the study of regional expenditure ceilings.

[96] DOCUMENT ON THE SUBJECT OF PHARMACEUTICAL GOVERNANCE [http://www.salute.gov.it/imgs/C_17_notizie_3567_listaFile_itemName_0_file.pdf]

In addition, there were changes in the field of pharmacovigilance: the diffusion in the adoption of the price-volume mechanism; the updating of the criteria for innovative drugs; and the revision of the 2001 CIPE resolution on bargaining criteria of the price of drugs.

Furthermore, the former Ministry of Health added that one of the main objectives is the obtaining of savings through the correct allocation of resources. Giulia Grillo then stated that: "*It is clear then that if within this allocation a quantity of resources is released to be used not only for the pharmaceutical industry but also for others for other sectors of health, no one will uphold rights but rather we intend to expand them. The cost-benefit ratio of a device and a drug is always clear to us*". From this point of view, the savings forecasts are € 2 billion.

The Document provides three major addresses: "*addresses that can be implemented quickly by AIFA under the current legislation; addresses for which detailed application documents are required; and addresses for which they are made necessary regulatory or administrative adjustments or even mere organizational nature within the Agency*"[97].

In the *TABLE 7- CHANGES IN PHARMACEUTICAL GOVERNANCE*, shown in the APPENDIX, we have gradually summarized how the Pharmaceutical Governance has changed.

[97] "*FARMACI: CAMBIA TUTTO. PREVISTI 2 MLD DI RISPARMI*", Luciano Fassari, 2018. [http://www.ilfarmacistaonline.it/scienza-e-farmaci/articolo.php?articolo_id=68884]

3.2.3. The Italian proposal for pricetransparency

The Former Minister of Health, Giulia Grillo in February 2019, sent a proposal for a resolution to the WHO regarding the transparency of the price of the medicines.

The decision has been taken by the former Minister for thus explained reason: "*The draft resolution I sent to the WHO stems from the need to address the issue of lack of transparency in the field of drugs and in particular how to arrive to price formation: in Europe, since 1988, the Transparency Directive was issued, which unfortunately never achieved the objectives of transparency that it had set itself in. Since then there have been numerous, albeit fragmented, initiatives on this important issue which, however, it has never been addressed with a systematic and common international approach, so I sent this resolution proposal to the WHO*".

The main requests made to the WHO concern: collecting and analysing data on the results of clinical studies and on the adverse effects of drugs and other health technologies; providing governments with a forum for sharing information on drug prices, revenues, research and development costs, public sector investments and research and development subsidies, marketing costs and other related

information;provide crucial information on the patent scene; and, finally, take further action through meetings and forums to further progress[98].

The proposal has aroused interest among the different countries participated in the Assembly and it has led to the approval of a resolution by the World Health Assembly(WHA)[99]. This resolution invites all countries to observe the importance of the availability of information on the drugs prices and other health products, so that a basis for the work and for the decisions of the bodies that buy or reimburse products can be assured.

Specifically, the proposal invites the propagation of information on the prices of healthcare products and on the elements that contributed to determining these prices, including the costs and public contributions of research and development.

The proposed transparency of drugs by the Italia Ministry is a small step to obtain a great result and to achieve a concrete success.

Moreover, Italy has a long experience in managing data on prices and consumption of drugs, as it has always used, like many countries, the

[98] "*Trasparenza del prezzo dei farmaci, il ministro Grillo presenta la proposta di risoluzione inviata all'OMS*": [http://www.salute.gov.it/portale/news/p3_2_1_1_1.jsp?lingua=italiano&menu=notizie&p=dalministero&id=3670]

[99] The World Health Assembly is the decision-making body of WHO. Itisattended by delegations from all WHO MemberStates and focuses on a specifichealth agenda prepared by the Executive Board. The Health Assembly isheldannually in Geneva, Switzerland. [https://www.who.int/about/governance/world-health-assembly]

methodology based on the ATC classification and the concept of DDD[100]. This has also been recalculated, so that the national situation could be better reflected.

To conclude, the resolution requires the participation of some countries that may not even be part of the EU, in fact, Italy has frequent relations and contacts with Tunisia, which has a very compelling import and pricing system for drugs[101].

[100] The defineddaily dose (DDD) isusedas a unit for measuring a prescribedamount of a pharmaceutical. DDD isbased on the amount of an agent or a pharmaceutical, whichtypicallyisused for the mainindication of adults per day.

[101] Ginevra approva la proposta italiana di trasparenza sui prezzi dei farmaci, 2019. [http://www.ricercaepratica.it/r.php?v=&a=31489&l=337452&f=allegati/00000_0000_00/fulltext/31489_Politichedelfarmaco_Reggi_Anticipazione.pdf]

3.3. THE ASPEN CASE IN A COMPETITIVE MARKET

A perfectly competitive market has several features, such as many buyers and sellers on the market, who offer perfectly replaceable goods; and the company cannot influence the price with its own decisions.

However, the pharmaceutical sector remains among the first industries sanctioned in the economy due to abuses of dominant position and instrumental use of patents.

Indeed, in the annual report of the Authority for competition and the market presented in Parliament, in 2013, these issues has been reported[102].

The report has shown that in 2012 the Antitrust Authority imposed sanctions of around 182 million euros, of which 170 million for anti-competitive crimes.

Giovanni Pitruzzella declared that the Authority pays particular attention to the pharmaceutical sector, since it is a typical sector of tension between the protection of intellectual property and competition. He also added that protection is essential for innovation, but an abusive use of this could prevent competition. Moreover, high price increases can occur with negative repercussions on the public budget.

Finally, the Commission has illustrated the prejudices to competition, that can be established in the market, reporting in particular examples of abuses of dominant position[103]. (AGCM, 2013)

---

[102] *"Relazione annuale sull'attività svolta",* Autorità Garante della Concorrenza e del Mercato, 2013.
[http://www.quotidianosanita.it/allegati/allegato1492449.pdf].

As analysed in the previous chapter, the Aspen Pharmacare Holdings Limited has been accused of abuse of dominant position for Cosmos drugs.

In fact, the Group imposed excessive prices for these drugs, by means of an unfair and aggressive negotiation strategy.

The drugs were classified according to a chemical anatomical therapeutic classification, ATC and due to this analysis the Court considered that the company is the only producer for which the SSN can refer[104].

In the following paragraph we will try to explain some situations that may occur in the pharmaceutical sector. In particular, we will analyse how conflicts of interest, information asymmetry and monopoly can be themes that favour the abuse of a dominant position.

3.3.1. Conflicts of interest in the pharmaceutical field

In our economic analysis, conflict of interest has been important to consider, in order to verify it in the Aspen case.

The issue of conflict of interest (CdI) has been recorded in the international scientific literature and it has been related to the different areas of the industrial economy. However, in our research there are the possibilities of finding conflicts

---

[103] "*Antitrust. Il settore farmaceutico resta tra i più sanzionati. Abusi e uso strumentale del brevetto*", 2013. [https://www.quotidianosanita.it/governo-e-parlamento/articolo.php?articolo_id=15578]

[104] "*The Tar Lazio'sjudgement in the italianaspen case. On the imposition of unfairprices under art. 102(a)Tfeu*", Michela Angeli, 2017 [http://iar.agcm.it/article/view/12861] (Dirindin, Rivoiro, & Fiore, 2018)

of interest in the pharmaceutical sector. In fact, this theme is widely present in the field of health protection.

A first historical definition has been given by Dennis F. Thompson, founder and director of the Harvard University Center for Ethics and the Professions, which defines the conflict of interest as "*a set of conditions by which a professional judgment concerning a primary interest tends to be unduly influenced by a secondary interest*" [Thompson, 1993].

More specifically, Marco Bobbio, Italian scholar of the subject under consideration, proposed a more articulated definition, stating that the conflict of interest is "*a condition in which the judgment of a health professional, concerning a primary interest - namely health of a patient or the veracity of the results of a research, tends to be influenced by a secondary interest, such as financial gain or a personal advantage*" [Bobbio, 2004][105].

In particular, these choices have not always been made by personal contact, but sometimes it is necessary to protect the patient himself.

It is the case analysed in this report: Aspen Case. In fact, the Aspen Group raised the prices of Cosmos drugs by threatening to withdraw an essential drug from the market if AIFA had not agreed to renegotiate the price of the same drug.

[105] "CONFLITTO DI INTERESSE E SALUTE, come industrie e istituzioni condizionano le scelte del medico", N. Dirindin, C. Rivoiro, L. De Fiore, 2018, pp.12-13.

Indeed, Aspen had stated that in the event of failure to reach an agreement on the price, it would not have commercialised these drugs in Italy, but would have made the same drugs available to Italian patients at the price charged in other Member States, even higher than what could have been renegotiated by AIFA. Consequently, AIFA has been forced to accept those prices.

In this regard, the World Health Organization (WHO) has produced a definition, that could be an explanation of AIFA's behaviour: "Conflict of interest means that the expert or his partner (or the spouse or other person with whom there is a close personal relationship) or administrative unit with which the expert has an employment relationship, has a financial or other interest that could unduly influence the expert's decision on the matter under consideration" [WHO, 2010].

The definitions given above are examples present in some pharmaceutical cases and which summarise the main characteristics to define the concept of conflict of interest. In fact, the CdI is a condition because it is a set of circumstances, a situation of risk very widely present in the health sector.

In order to avoid these situations, over time different positive experiences of regulation of the relationships between industries and associations have developed. Since 2000, the Long-term Medical Conditions Alliance (LMCA)[106] has provided guidelines that can help individual associations in relations with the

[106]Itis a supranationalassociationthatbringstogether more than 100 differentrealitiesrepresenting just asmanyclinicalconditionscharacterized by chronocytes.

pharmaceutical industries. LMCA considers that collaboration is necessary and must be regulated, since it has a useful interaction to protect the real interests of patients. For this reason, the importance of using written contracts is maintained, so that no conflict of interest is verified by either party[107]. [N. Dirindin, C. Rivoiro, L. De Fiore, 2018].

3.3.2. Information asymmetry and monopoly

In economic analysis, information asymmetry deals with the study of decisions in transactions where one party has more or better information than the other. This asymmetry creates an imbalance of power in transactions, which can sometimes cause the disappearance of the deal, a kind of market failure in the worst case.

Information asymmetry is a widespread situation in the pharmaceutical industry, especially as regards the relationship between the patient and the professional. Similarly, the relationship between researchers and financiers has been characterized by information asymmetries, especially in decision-making situations and in negotiations[108].

In the Aspen case, the negotiation of the price of drugs with the AIFA regulator was emblematic. In fact, if the negotiation had not reached an agreement, the drug would have been placed in *Class C*, so the economic costs of the purchase would

[107] "CONFLITTO DI INTERESSE E SALUTE, come industrie e istituzioni condizionano le scelte del medico", N. Dirindin, C. Rivoiro, L. De Fiore, 2018, page 111.

have ended up entirely burdening patients, or regional funds not covered by the national health fund.

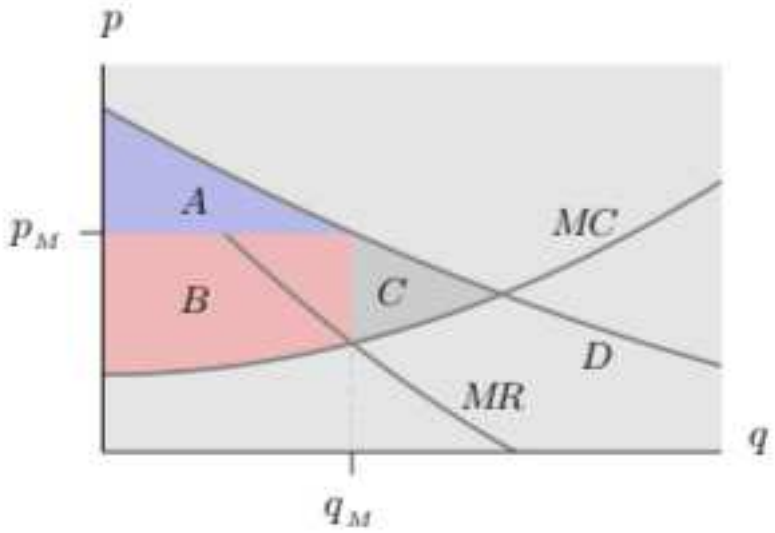
For this reason, the regulatory framework has favoured the existence of a marked information asymmetry to the advantage of the pharmaceutical industry. This informative asymmetry has been used by the pharmaceutical company to increase the price of drugs already on the market in an unjustified way.

In this perspective, the Authority has positively assessed some provisions contained in the 2019 Budget Law, which aim to rebalance the asymmetries of contractual power between AIFA and the pharmaceutical companies. In particular, it refers to the new criteria for negotiating drug prices, assuming that in the future there will be the possibility of removing the distortions, with consequent benefits for the SSN and for consumers[109].

Another market failure is caused by the monopoly. From the theoretical point of view, the monopolist places the price (p) at the level in which RM = CM. However, the monopolistic equilibrium (qM) is lower than the efficient one (qC), which is why it is inefficient.This inefficiency is found in area C, often referred to as the Harberger triangle, which adds all the lost p-MC surplus resulting from the missing operations, as shown in the graph below:

[109] *"Autorità garante della concorrenza e del mercato (AGCM). Relazione annuale sull'attività svolta nel 2018"*, Marco Boni, 2019.

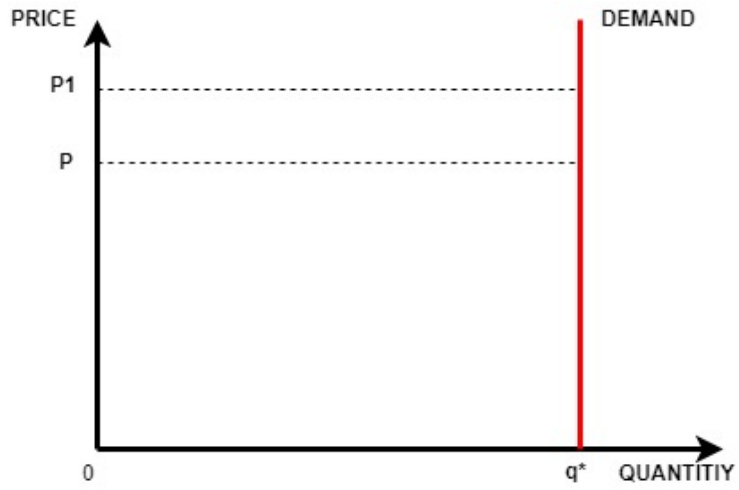
Figure 6 MONOPOLY MARKET EQUILIBRIA



[Source: Cabral, L. M., (2017) *Industrial Organization*, MIT Press: Cambridge, Chapter 5, page 2]

In the pharmaceutical sector Aspen Group is considered a monopolist in its relevant market since there are no other products made with the same molecule as the Cosmos drug package, so they cannot be replacing directly. In fact, on the demand side, these drugs differ from other alternatives offered in the hospital. The main features that make Aspen a monopolist in its relevant market are: high tolerability; domestic useand rigidity of demand. This is due to therapeutic continuity, which makes demand inelastic despite the presence of alternatives. Regarding the rigidity of demand, it is typical of the pharmaceutical sector, in particular with regard to life-saving drugs. As shown in the graph below, the rigid question is given by e = 0, so it is represented by a straight line:

Figure 7 Perfectly Inelastic Demand



[Source: our elaboration based on Perfectly Inelastic Demand]

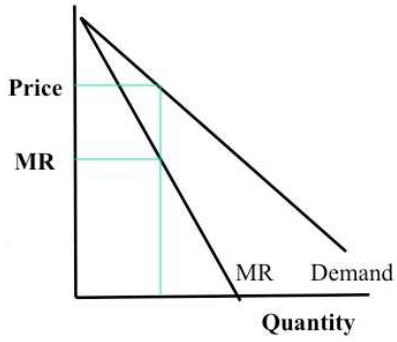
The quantity required of the asset does not change with the price and it is constant: whatever increasing the price, the consumer always buys at the same quantity of the good.

Therefore, the absence of therapeutic substitutability between the medicinal products considered and other products allows us to encompass the relevant market at the level of a single active principle (ATC5).

3.3.3. Inefficiency of monopoly

A monopolistic market is characterized by a single seller, which establishes the selling price of the product (price-maker). For this reason, the monopolist has a downward sloping demand curve as there is a compromise that the monopolist has to consider: for increasing his sales he is forced to reduce prices. Another main factor is the marginal revenue curve which is always below the demand curve because marginal revenues from the sale of additional production units are lower than its price, as shown in the figure below:

Figure 8 A SINGLE PRICE MONOPOLIST



[Source: MONOPOLY GRAPHS[110]]

From this point of view, the monopoly is considered inefficient because it places prices too high with respect to allocative production with consequent damage to the consumer. Furthermore, as there are no substitute products, many companies take advantage of their market position to obtain greater profits.

[110]Retrieved from: https://courses.byui.edu/ECON_150/ECON_150_Old_Site/Lesson_08.htm

By definition, Monopolies and companies that collude to act as monopolies reduce competition and create market inefficiency.

As a result, the government can assess a monopolist market based on the number of companies in the sector and barriers to entry or based on market performance or behaviour, that resulted with prices inefficiencies.

In a situation of monopoly, the government can pursue a variety of options: to interrupt the monopoly according to the antitrust laws; to regulate the monopoly; or to ignore, if they anticipate that the monopoly will be short-lived or will have a negligible impact[111].

In the case of the pharmaceutical sector, there have been several directives aimed at regulating prices, as highlighted in the previous paragraphs.

The Authority intervened to avoid negative impacts on the Servizio Sanitario Nazionale, but above all to guarantee the fundamental right of citizens' health.

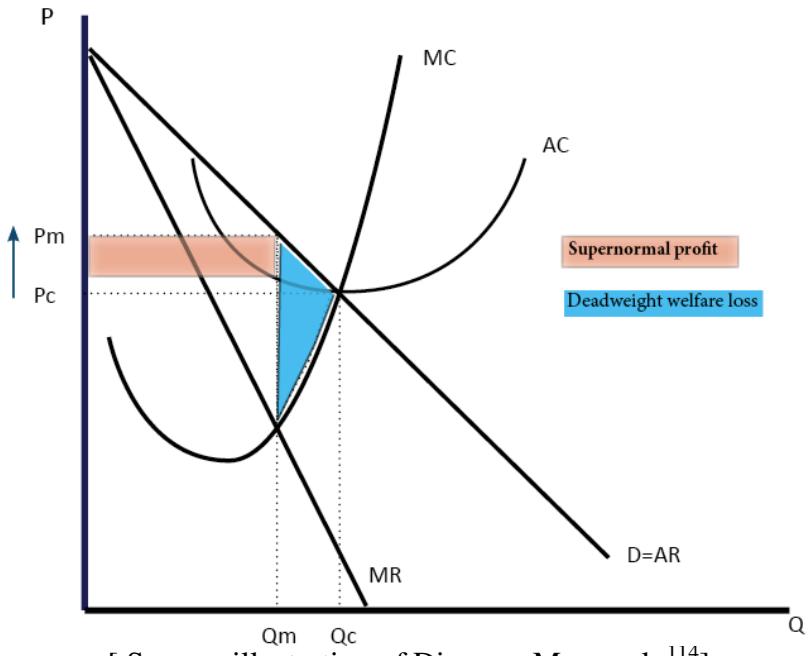
In some cases, the pharmaceutical industry attributes the increase in drug prices to the need to recover research and development costs. However Aspen Group has made a deal with AIFA without proper cost justification, but reporting as one ofreason the need to align prices with those of other European countries[112].

[111] Section 03: Antitrust and Regulation [https://courses.byui.edu/ECON_150/ECON_150_Old_Site/Lesson_08.htm]

[112] "*Antitrust. Bilancio 2016 "Puniti gli abusi di posizione dominante". Tra tutti il caso Aspen, multata per 5 mln di euro per aver aumentato fino al 1.500% il prezzo degli antitumorali*", 2017. [https://www.quotidianosanita.it/governo-e-parlamento/articolo.php?articolo_id=50796]

In conclusion, the monopoly situation is not Pareto-efficient[113], as one cannot increase the well-being of someone without diminishing that of others.

Figure 9MONOPOLY GRAPH



[Source: illustration of Diagram Monopoly[114]]
[KEY→ Red area = Supernormal Profit (AR-AC) * Q
Blue area = Deadweight welfare loss (combined loss of producer and consumer surplus) compared to competitive market]

Nevertheless, consumers would be willing to pay a price higher than the cost of production, so that they can take advantage of the good, but this is an immoral and non-regulatory situation.

[113] Pareto efficiency or Pareto optimalityis a state of allocation of resources from whichitisimpossible to reallocate so as to makeanyoneindividual or preferencecriterionbetter off withoutmakingatleastoneindividual or preferencecriterionworse off.
[114]Retrieved from: https://www.economicshelp.org/microessays/markets/monopoly-diagram/

3.4. ECONOMIC AND ETHICAL DECISION

A final aspect that deserves consideration is the combination that is generated between ethics and the economy in the pharmaceutical sector.

Drugs are primary goods, which in many cases guarantee solutions to diseases that can compromise the health and life of citizens. The right to life is inalienable and it is protected by many jurisdictions and statutes, such as the Charter of Fundamental Rights of the European Union.

However, in many circumstances, the illicit behaviour of pharmaceutical companies has "threatened" this right to life.

Aspen case has been considered an example, because of with the increase in the prices of the Cosmos drug package, has almost made the drugs belonging to the *C class*. This would have led to an inconvenience since the drugs would have been totally at the consumer's expense and with prices still higher than those proposed at regulator of prices. In fact, in this case, AIFA had agreed to increase prices, mainly to protect consumers.

In this situation, the State has been assumed the burden of over 70% of the expenditure on drugs,with the aims to remain universalistic and supportive in health care. Consequently,maintaining this balance requires an ethical reflection on the system of society values.

The Authority has the duty to establish how much it is willing to pay for drugs, in particular considering the rights to take care the patient, who needs life-saving

drugs. The trade-off of the rights to the care and the possibility that the drugs may weigh on the consumers'costs has been relevant[115]. (L.Pani, 2015)

In the Health Meeting, a program dedicated to health issues, the challenge that has emerged is thematching of ethics and universal access to the treatments.

The medicine is a resource, because if a company operates lawfully and invests in research and development it can make profits. Different bodies, such as Banco Farmaceutico, collaborate with companies to make drugs accessible to everyone, especially for the weaker segments of the population.

The goal is to consider drugs as a primary good, but also as a source of income: in the pharmaceutical sector, this good is necessary and ethics must be safeguarded.

GiulianoSalvioni, counsellor of Banco Farmaceutico has been explained as follows: "*In addition to drug collection days and agreements with pharmaceutical companies we also have partnerships with numerous pharmacies for the collection of valid medicines, donated by citizens only in the presence of certain requirements and equipped of a tracking method. A system that only in 2017 made it possible to collect over 105 thousand packs that would otherwise have been thrown away*"[116]. (I. Nava, 2017)

---

[115] "L'INNOVAZIONE SOSTENIBILE, il farmaco e le sfide per il futuro del nostro Servizio Sanitario Nazionale", Luca Pani, Milano, 2015.
[https://www.aifa.gov.it/documents/20142/516919/innovazione_sostenibile_0.pdf/6b5b2a46-bac8-4987-d8a0-d927308bd1c3]

[116] "Alleanza tra profitto ed etica per l'accesso universale ai farmaci", Ilaria Nava, 2017.
[https://www.digitalmarketingfarmaceutico.it/alleanza-profitto-ed-etica-accesso-universale-ai-farmaci/]

The Farmindustria in its ethical code "*recognizes the value of the person and of solidarity towards civil society, of scientific community, the world of work and health as a whole. It pursues the development of the sector, tackling its scientific, ethical and economic problems. It promotes the value of the drug from a therapeutic, industrial, economic and social point of vie*" [CODE OF ETHICS].

A good regulation, through the intervention of the Authority and the competent bodies, has the purpose of avoiding these behaviours and the consequences that they entailed, not only as regards the costs incurred but especially to guarantee the health of the citizens.

3.4.1. Analysis of Aspen pricing methodology

The analysis of Aspen's price is necessary to assess the unfairness of the prices examined.

The prices charged by the company have been considered abusive because the Group had benefited from its market position to gain commercial advantages. The examination was conducted according to the method of European jurisprudence.

The assessment of the prices applied by Aspen has been carried out according to a two methodology, corresponding to one of the methods applicable in order to establish whether a price is abusive.

In particular, it was assessed whether there was an excessive disproportion between the cost actually incurred for the production of the good and the price actually requested by the company.

The first methodological analysis is based on an analysis of disproportion between prices and costs measured through the gross contribution margin of each single Cosmos drug; while the second examines the disproportion between the prices applied and the costs incurred by Aspen by measuring the difference between revenues and the cost plus, or the sum of direct costs, of a share of indirect costs attributed to the products and a measure of profitability of the company.

The prices assumed as the basis of the calculation, both in the first and in the second of the methodologies have to be considered net of the statutory discounts and the distribution margin recognized by Aspen to LFM.

The disproportion of the imposed price must be assessed with reference to a measure of the total costs incurred by the company for the realization of the product. It includes primarily the variable direct costs (in the item cost of sales or cost of goods sold, COGS) and the fixed direct costs, considering a portion of the indirect costs incurred by the company.

For an overall measurement of the cost faced by the company, various indicators of company profitability has to be considered, which vary from return on

investment (ROI, ROE, ROCE, WACC)[117]and from sales profitability rates (ROS, contribution margin)[118].

Furthermore, on the demand side, qualitative factors are important, for instance the improving the product from a therapeutic point of view. Instead, on the supply side, the analysis of potential competitive pressures capable of conditioning the behaviour of the company has been relevant. It has been taken into account that there is no existence of substitute goods, because of they are life-saving drugs: the willingness to pay for life-saving drugs without a therapeutic alternative can only tend to infinity, powerfully justifying any increase in prices.

[117] ROI, Return on Investment; ROE, Return on Equity; ROCE, Return on Capital Employed; WACC, WeightedAverageCost of Capital.
[118] ROS, Return on Sales.

3.4.2. Data analysis of the price decision

The consolidated financial statements of Aspen Pharma Holding Limited of 2014-2015 are:

*TAB 7 CONSOLIDATED FINANCIAL STATEMENTS**

	Financial Statements APHL	June 2014	June 2015
PQ	REVENUE	2.079	2.654
DCQ	COST OF SALES (DIRECT COSTS)	1.112	1.387
CM=PQ-DCQ	**CONTRIBUTION MARGIN**	966	1.268
a)	SELLING AND DISTRIBUTION EXPENSES	310	413
b)	ADMINISTRATIVE EXPENSES	116	207
c)	OTHER OPERATIONG EXPENSES	66	67
d)	OTHER OPERATING INCOME	49	40
GOP= CM	**GROSS OPERATING MARGIN**[119]	523	621
e)	INVESTMENT INCOME	20	28
f)	FINANCING COSTS	95	169
Pre-tax profits= GOP+e)-f)	**PRE-TAX PROFITS**	448	480

[Source: our elaboration on Annual financial statement 2014 and 2015 of APHL, AGCM,2016 gathering of 29th September 2016, p. 38]

* APHL financial statements are valued in South African rand (ZAR).
The ZAR / € exchange rates indicated by the Aspen group in its integrated report were applied to these values.

[119] The grosscontributionmargin, alsocalledgrossmargin (gross profit if positive), represents the differencebetween the net value of sales and the cost of sales of a givenproduct or of the products of a company.

Cosmos products generated a positive contribution to the group's profit even before the renegotiation of their price, based on the gross contribution margin. From the Sales and Distribution signed in 2009 between GSK and AGI, it indicates that Cosmos products worldwide produced a gross margin of around €1-50 million.

The "Value by product by market" of Italian Market indicates that, Cosmos drugs produced a gross margin of approximately € 600,000-700,000, a positive value at least equal to 20-30% of the sales value. These data are summarized in the table below:

TAB 8 CONTRIBUTION MARGIN OF ASPEN PRODUCTS BEFORE RENEGOTIATION

ITALIAN MARKET 2013				
PRODUCT	ALKERAN / MELPHALAN	LANVIS/ THIOGUANINE	LEUKERAN/ CHLORAMBUCIL	PURINETHOL/ MERCAPTOPURINE
SALES	200-250	60-70	90-100	200-250
REVENUE	50-100	1-50	50-100	50-100
GROSS PROFIT	100-150	1-50	1-50	100-150
RATIO ANALYSIS[120]				
GROSS PROFIT %	50-60%	30-40%	20-30%	60-70%
COST OF SALES%	40-50%	60-70%	79-80%	30-40%

[Source: Our elaboration on AGCM,2016 gathering of 29th September 2016, p.40]

In particular, it shows that for Italy in 2013, the contribution margin of the drugs in question was between 20-30% for Leukeran and around 70-80% for Purinethol.

[120] In the ratio analysis, the absolutevalue of the contributionmargin and the costs of sales iscompared to the value of sales, obtainingtwopercentageindices "gross profit%" (contributionmarginas a percentage of sales) and the cost of sales%.

In conclusion, the analysis implies that the prices of Cosmos drugs applied by Aspen in Italy already before the negotiation with AIFA exceeded the economic value of these products, measured by the set of direct and indirect costs incurred by Aspen for their realization.

According to the methodologies used, the Cosmos drugs havebeen already profitable, with values between 20% and 80%, before the required increases. In addition, it has emerged that from the increases in the prices of drugs, Aspen has obtained surplus revenues for percentages between 100% and 400%.

This means that, once applied to sales revenues of Cosmos productsthe percentages of increase approved by AIFA in March 2014, ranging from + 300% to + 1500%, the revenues obtained by Aspen for the sale of Cosmos drugs in Italy exceed to a considerable extent the overall costs attributable to the products in question, rendering them unfair in the Italian market.

CONCLUSION

The pharmaceutical sector is a complex field that requires adequate regulation and necessary control by organizations.

To perform the analysis of the Aspen case, we mostly referred to the documentation provided by AGCM. In particular, we based our considerations on the opinions that emerged inthe proceeding, which contains the information of the parties.

Aspen Pharmacare Holdings Limited has operated in the European market since 2009, after the acquisition of the Cosmos drug package from GSK.

The agreement between the two pharmaceutical companieshas been observed during the ruling, however, the sensitive data in the bargaining has not be disclosed to third parties. Indeed, GSK's decision to sell the package of life-saving medicines was considered peculiar. First, because GSK is a multinational company active in the production and distribution of medicines; second, because it has been shown that the Cosmos drug package is profitable source of income. Nevertheless, as highlighted, due to costs of patent restrictions and research and development, some pharmaceutical companies have to make deals to amortise costs.

The Cosmos drug package was the basis of the proceeding, as in 2013 the multinational company requested increase in price to the regulator, AIFA.

The proposal has been presented because Aspen claimed that the investment in drug acquisition had not yield a return yet. In the absence of agreement, the multinational corporation decided to replace the drugs in the *class C*, at the expense of consumer.

Therefore, AIFA had to decide whether to accept the agreement, in order to prevent consumers or distributors, such as pharmacies, from charging the full cost of these life-saving drugs.

The AGCM began a preliminary investigation of the case in 2014, since Aspen had increased the Cosmos drugs prices by almost 1050%. AIFA, Altroconsumo and other organizations participated in the proceeding, because of the relevant information provided.

In 2016, Aspen Pharmacare Holdings Limited was accused of abuse of dominant position, according to article 102 of the TFEU, with a financial sanction of 5 million euros.

Over time, AIFA and Aspen aimed to reach an agreement on the new stipulation of Cosmos drugs prices. At the beginning, the multinational corporation has been accused, due to a lack in the fulfilment of the requests made by the regulator. As often mentioned, Aspen stated that an increase was necessary considering the above-mentioned characteristics, such as the costs incurred.Nevertheless,the agreement was formalised in 2018.

The analysis of the relevant market, in which the Aspenoperates, was essential for defining the choice of the new prices.

The characteristics of Cosmos drugs, such as high tolerability, domestic use, and rigidity of demand have been unique and irreplaceable. Even GSK, the former holder of the drugs examined, confirmed that Cosmos drugs have no therapeutic alternative for those cancer patients suffering from critical illnesses. It is for these reasons that Aspen is a monopolist in its relevant market.

Consequently, in order to "satisfy" all the parties, the prices of the Cosmos package increased compared to those of 2013, but with a reduction of a minimum of 29% to a maximum of 82% compared to 2014 prices.

The study of new frontier of price transparency is the result of our economic analysis. In the pharmaceutical sector one of the main problem is sharing information among the participants: the former Health Minister Giulia Grillo, in order to develop a platform, in which all the prices and patent information of the drugs are recorded, sent a proposal to WHO.

Furthermore, deepening the analysis: conflict of interest, presence of information asymmetry and inefficiency of the monopoly have been studied specifically, acknowledging a correlation between Aspen case and the unfair practices.

In particular, conflict of interest has been part of the agreements among the parties: AIFA acted for protecting mainly the consumers. So as to create a

regulated and necessary collaborationbetween organizations and pharmaceutical companies, the introduction of new type of contract could be a solution.

Information asymmetry has been used by the pharmaceutical company Aspen to increase the price of drugs in an unfair way. In this perspective, the Authority has evaluated new criteria for the negotiation of drug prices, with the purpose of expunge injustices, with consequent benefits for the national health system and for consumers.

The inefficiency of monopoly has been verified through the inelastic demand of Cosmos drugs: increasesthe price, without change the quantities. However, being unfair prices, Aspen's monopoly is more specifically uneconomical.

In the final part of the analysis, two methodologies, for identifying the excess prices, have been applied: the measurement of disproportion between prices and cost, through gross margin, i.e. a performance indicator; and the evaluation of company's profitability, calculating the difference between revenues and cost plus.

The analysis hasdemonstrated that the prices of Cosmos drugs applied by Aspen in Italy exceeded the economic value, also before the agreements with AIFA. This means that, once applied to revenue from sales of Cosmos products, the percentage increase,approved by AIFA in March 2014,significantly exceed the total costs attributable to the products in question.

To conclude, in order to safeguard citizens and the inalienable right to life, all the phases of pharmaceutical market regulation have been have covered.

The aim has been to highlight how Authory acts in a presence of dominant position and other unfair practices, in particular, focusing in the pharmaceutical sector. Moreover, it has been emphasized the importance of formulating innovatedregulations, appropriate for a legal competitive market.

BIBLIOGRAFICAL REFERENCES

AGCM. Retrieved from Autorità Garante della Concorrenza e del Mercato: https://en.agcm.it/en/about-us/

AGCM.(1990). Retrieved from Legge 10 ottobre 1990, n. 287 "*Norme per la tutela della concorrenza e del mercato":* https://www.agcm.it/chi-siamo/normativa/legge-10-ottobre-1990-n-287-norme-per-la-tutela-della-concorrenza-e-del-mercato

AGCM. (2006, February 8). proc. A363- Glaxo Principi Attivi, provv. n. 15175.

AGCM. (2007, March 21). proc. A354-Merck Principi Attivi, provv. n. 16597.

AGCM. (2013, March 31). "*Relazione annuale sull'attività svolta"*. Retrieved from *Quotidiano Sanità*: http://www.quotidianosanita.it/allegati/allegato1492449.pdf

AGCM. (2016, September 29). *A480*-"*Aspen/Increase in drug prices*". *AGCM- Ruling n. 26185* .

AGCM. (2016, December 7). "*Pfizer/ Flynn Pharma*". *proc. CE/9742-13* .

AGCM. (2018, June 13). *A480B- "Increase in drug prices- Non compliance"*. Retrieved from AGCM- ruling n. 27209 .

AMGROS. *About amgros.* Retrieved from https://amgros.dk/en/about-amgros/

Angeli, M. (2019, Febbraio 28). "*The TAR lazio's judgement in the italian aspen case on the imposition of unfair prices under ART. 102(A) TFEU.* Retrieved from AGCM: http://iar.agcm.it/article/view/12861

Antitrust. Bilancio 2016 *"Puniti gli abusi di posizione dominante. Tra tutti il caso Aspen, multata per 5 mln di euro per aver aumentato fino al 1.500% il prezzo degli antitumorali"*. (2017, may 16). Retrieved from Quoditiano Sanità:

https://www.quotidianosanita.it/governo-e-parlamento/articolo.php?articolo_id=50796

ASPEN.Retrieved from Sustainability Overview: https://www.aspenpharma.com/sustainability-overview/].

ASPEN. *Aspen Pharma.* Retrieved from https://www.aspenpharma.com/group-overview

ASPEN.(*Commentary*).Retrieved from Aspen Holdings: http://www.aspen-reports.co.za/results/aspen-results-2019/commentary.php

Balduzzi, R. (2016, marzo 31). *Sanità 24-Il sole24ore.* Retrieved from Il manuale per capire la politica del farmaco: https://www.sanita24.ilsole24ore.com/art/lavoro-e-professione/2016-03-31/il-manuale-capire-politica-farmaco-115314.php?uuid=ACGKtixC&refresh_ce=1

Beukes, S. (2019, March 8). "*Aspen's encouraging emerging market growth*".

Boni, M. (2019). "*AGCM. Relazione annuale sull'attività svolta"*.

CAT. (2018, giugno 7). "*Pfizer e Flynn Pharma contro Competition and Markets Authority*". *case 1275-1276/1/12/17* .

Cavalli, R. (2017, agosto 4). *Legge sulla Concorrenza n. 124/2017.* Retrieved from Sanità Pubblica e Privata: https://www.periodicimaggioli.it/legge-n-1242017-settore-farmaceutico/

Codice Etico. Retrieved from Farmindustria: https://www.farmindustria.it/app/uploads/2017/10/codiceetico072013.pdf]

Cucinotta, A. (2018). "*La natura dei mercati, l'economia comportamentale e l'antitrust*". *Mercato concorrenza regole*, p. 199.

Danish Competition and Consumer Authority. (2018, January 31).

"*CD Pharma has abused its dominant position by increasing their price by 2,000 percent"*. Retrieved from Danish Competition and Consumer Authority: https://www.en.kfst.dk/nyheder/kfst/english/decisions/2018-cd-pharma-has-abused-its-dominant-position-by-increasing-their-price-by-2-000-percent/]

Decreto Legge n. 269. (2003, Settembre 30).

Retrieved from LexItalia: http://lexitalia.it/leggi/dl_2003-269.htm

Decreto Legislativo 24 aprile 2006, n. 219. (2006, giugno 21).

Retrieved from Camera dei deputati: http://www.camera.it/parlam/leggi/deleghe/06219dl.htm

Delsignore, M. (2014). "*La regolazione dei prezzi dei farmaci*".

Rivista della regolazione dei mercati, pp.192-194.

Diffidenti, E. (2019, maggio 28). *Sanità24-Il sole 24ore.*

Retrieved from Farmaci: l'Oms adotta la risoluzione dell'Italia sulla trasparenza dei prezzi: https://www.sanita24.ilsole24ore.com/art/dal-governo/2019-05-28/farmaci-oms-adotta-risoluzione-italia-trasparenza-prezzi-145755.php?uuid=ACTRKmJ&refresh_ce=1

Directive 2001/83/EC (6, November 2001).

of the European Parliament and of the Council on the Community Code relating to medicinal products for human use.

Retrieved from https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/directive-2001/83/ec-european-parliament-council-6-november-2001-community-code-relating-medicinal-products-human-use_en.pdf

Dirindin, N., Rivoiro, C., & Fiore, L. D. (2018).

"*Conflitto di interesse e salute, come industrie e istituzioni condizionano le scelte del medico"*.

EPO. Retrieved from European Patent Office: https://www.epo.org/about-us.html

European Coalition on Homeopathic & Anthroposophic Medicinal. Retrieved from https://www.echamp.eu/eu-legislationandregulationdocuments/directive_65-65-eec__-__consolidated_version.pdf

European Union. Retrieved from https://europa.eu/european-union/about-eu/history_en

Fassari, L. (2018). "*Farmaci: cambia tutto. Previsti 2 mld di risparmi"* Retrieved from Il farmacista online: http://www.ilfarmacistaonline.it/scienza-e-farmaci/articolo.php?articolo_id=68884

Ferrari, G. F., & Fausto, M. (2015). "*Diritto del farmaco- medicinali, diritto alla salute- politiche sanitarie"*.Retrieved from Academia.Edu: https://www.academia.edu/13443580/Diritto_del_farmaco__Indice_e_introduzione

Fondazioni Astrid e Magna Carta. (2014, febbraio 3). "*La politica del farmaco Quadro normativo, problemi, proposte"*. Retrieved from Quotidiano sanità: http://www.quotidianosanita.it/allegati/allegato7779097.pdf

"Gran Bretagna. Super multa a Pfizer per aver aumentato il prezzo di un farmaco del 2600%" (2016, December 2016). Retrieved from FEDAIISF: https://www.fedaiisf.it/gran-bretagna-super-multa-pfizer-aver-aumentato-prezzo-un-farmaco-del-2600/

GSK. Retrieved from https://www.gsk.com/

ISDB."*About the International Society of Drug Bulletins"*.Retrieved from https://www.isdbweb.org/what-is-isdb

ISTAT. (2019). "*Rapporto sulla competitività dei settori produttivi"*. Retrieved from ISTAT: https://www.istat.it/storage/settori-produttivi/2019/Rapporto-Competitivita-2019.pdf

Kim, J. H., & Scialli, A. R. (2011, April 19). "*Toxicological Sciences"*. Retrieved from https://academic.oup.com/toxsci/article/122/1/1/1672454

Luca, A., & Giovanni, P. (2019). "*La cura della concorrenza"*. Roma: LUISS, University Press.

"La Nuova Commissione Unica del Farmaco". Ministero della Sanità : http://www.salute.gov.it/imgs/C_17_pubblicazioni_250_allegato.pdf

Law no. 287(1990, October 10).*"Norme per la tutela della concorrenza e del mercato",* Retrieved from Gazzetta Ufficiale: https://www.gazzettaufficiale.it/eli/id/1990/10/13/090G0340/sg

Law no. 326(2003, November 2003). Retrieved from *Gazzetta Ufficiale*: https://www.gazzettaufficiale.it/eli/gu/2003/11/25/274/so/181/sg/pdf

Law no. 833(1978, December, 23), "*Istituzione del servizio sanitario nazionale*": http://www.comune.jesi.an.it/MV/leggi/l833-78.htm]

Magnano, R. (2017, gennaio 19). "*Farmaci e concorrenza, patto tra AIFA e ANTITRUST"*. Retrieved from *Sanità 24-Il sole 24ore*: http://www.sanita24.ilsole24ore.com/art/dal-governo/2017-01-19/farmaci-e-concorrenza-patto-aifa-e-antitrust-112459.php?uuid=AE9XVZD&refresh_ce=1

Ministero della Salute. "*Ministero della Salute"*. Retrieved from Documento in materia di Governance farmaceutica: http://www.salute.gov.it/imgs/C_17_notizie_3567_listaFile_itemName_0_file.pdf

Monopoly.Retrieved from: https://courses.byui.edu/ECON_150/ECON_150_Old_Site/Lesson_08.htm

https://www.economicshelp.org/microessays/markets/monopoly-diagram/

Nava, I. (2017). "*Alleanza tra profitto ed etica per l'accesso universale ai farmaci"*. Retrieved from Digital Marketing farmaceutico: https://www.digitalmarketingfarmaceutico.it/alleanza-profitto-ed-etica-accesso-universale-ai-farmaci/]

ORIFARM. Retrieved from about us: https://www.orifarm.com/

Pani, L. (2015). "*L'innovazione sostenibile, il farmaco e le sfide per il futuro del nostro Servizio Sanitario Nazionale"*. Retrieved from AIFA: https://www.aifa.gov.it/documents/20142/516919/innovazione_sostenibile_0.pdf/6b5b2a46-bac8-4987-d8a0-d927308bd1c3

PHT. Retrieved from Agenzia del Farmaco: http://www.agenziafarmaco.gov.it/content/pubblicato-gu-il-prontuario-della-distribuzione-diretta-pht

Quotidiano Sanità(2013):*"Antitrust. Il settore farmaceutico resta tra i più sanzionati. Abusi e uso strumentale del brevetto"*. Retrieved from: Quotidiano e Sanità: https://www.quotidianosanita.it/governo-e-parlamento/articolo.php?articolo_id=15578

Reggi, V. "*Ginevra approva la proposta italiana di trasparenza sui prezzi dei farmaci"*.Retrieved from Politiche del Farmaco: http://www.ricercaepratica.it/r.php?v=&a=31489&l=337452&f=allegati/00000_0000_00/fulltext/31489_Politichedelfarmaco_Reggi_Anticipazione.pdf

Regulation (EC)(2004, March 31). *No 726/2004 of the European Parliament and of the Council.*Retrieved from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32004R0726

Roberto, J. A., & Davde, S. "*Prezzi eccessivi ed iniqui nel settore farmaceutico. Il CAT britannico annulla la decisione della CMA nel caso Pfizer e Flynn"*

Retrieved from: https://www.dejalex.com/wp-content/uploads/2018/09/1.-Prezzi-eccessivi.pdf

Roosevelt Institute. Retrieved from Roosevelt Institute: https://rooseveltinstitute.org/towards-broader-view-competition-policy/

Salute, Ministero della Salute. (2019). "*Trasparenza del prezzo dei farmaci, il ministro Grillo presenta la proposta di risoluzione inviata all'OMS"*.

Retrieved from Ministero della Salute: http://www.salute.gov.it/portale/news/p3_2_1_1_1.jsp?lingua=italiano&menu=notizie&p=dalministero&id=3670.]

Servizio Sanitario Nazionale. Retrieved from salute.governo http://www.salute.gov.it/portale/lea/dettaglioContenutiLea.jsp?lingua=italiano&id=5073&area=Lea&menu=vuoto"

Sherman Act. Retrieved from documents.gov: https://www.ourdocuments.gov/doc.php?flash=false&doc=51

Supreme Court of United States. (n.d.). Retrieved from About the Court: https://www.supremecourt.gov/about/historyandtraditions.aspx

TFEU. "*Treaty on the Functioning of the European Union"–*

"part three: union policies and internal actions - title vii: common rules on competition, taxation and approximation of laws". Retrieved from EurLex:https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:12008E102

"The competition and consumer protection commision".

Retrieved from Citizens Information : https://whatsnew.citizensinformation.ie/2014/11/07/the-competition-and-consumer-protection-commission/]

Von Hayek, F. (1989). "*Legge, legislazione e libertà"*. Milano.

WHA. *World Health Assembly.* Retrieved from World Health Organization: https://www.who.int/about/governance/world-health-assembly

WHO.*Word Health Organization*. Retrieved from https://www.who.int/

APPENDIX

TABLE 8 CHANGES IN PHARMACEUTICAL GOVERNANCE

a) Review of the handbook	It is therefore necessary for AIFA to verify the handbook of medicines eligible for reimbursement of the SSN and included in the PHT. In addition, AIFA must also investigate customized doses with respect to the needs of citizens for an appropriateness of use.
b) Equivalent drugs and transparency lists	AIFA must produce a detailed informative report on equivalent medicines, so that there is an appropriate consumption. The report must include public spending, price variability and patient characteristics.
c) Bio similar drugs	Such as generic medicines, AIFA must provide the same information space for the use of biological and bio similar drugs.
d) The purposeful role of AIFA in the identification of therapeutic equivalences	The Regions can proceed to make regional competitions in equivalents, AIFA will have to promote the sharing of regional experiences.
e) Operation of the AIFA registers	It is necessary to have a web-based register quickly, especially for drugs that have higher SSN reimbursement prices and for drugs with benefit-risk profiles. Furthermore the information recorded must be simplified, while those that have a risk sharing (MANAGED ENTRY AGREEMENT, MEA) can be complex.
f) Sharing with the Regions of the data collected in the AIFA Registers and of the	The AIFA will have to make the data available in compliance with the privacy protection legislation and will have to make the data used by OsMed available to the Regions so that they can make

regional data of OsMed[121]	comparisons and in-depth analyses independently.
g) Independent research and information, and pharmacovigilance activities	AIFA must prepare an activity plan annually in order to guarantee independent information to doctors and to strengthen the role of the SSN. AIFA also prepares an analysis of the scientific information activities on pharmaceuticals carried out in Italy by pharmaceutical companies.
h) Relationships with drug companies	AIFA must ensure the efficiency of the procedures in order to guarantee reliable times for examining the requests for opinions.
i) Scientific advice and conflicts of interest	AIFA participates in scientific advice activities conducted by the EMA and in multinational scientific advice activities.
l) Horizon scanning activities	It is necessary to use the information available at the EMA level on the drugs that are being approved to carry out a so-called "horizon scanning" activity to manage arrival times.
m) Diffusion in the adoption of the price-volume mechanism (P/V)	The price-volume mechanism must be defined when the AIFA price negotiation takes place, also providing for subsequent periodic negotiations during patent coverage, also in relation to the possible extension of the therapeutic indications.
n) Patent-linkage and adaptation of Italian legislation to European directives	The Ministry of Economic Development guarantees the availability of up-to-date and timely information on patent expiration dates of patented drugs, so that "transparency lists" can be prepared.
o) Evaluation of innovative drugs	It is necessary that AIFA prepare an updated version of the innovation document, which is also useful for the bargaining activities conducted by the Agency itself.
p) Role and operation of	In any case, it is necessary to adopt simplified

[121] The National Observatory on the Use of Medicines (OsMed) ensures the monitoring of the pharmaceuticalexpenditureagreedatnational and regionallevel. [https://www.aifa.gov.it/osservatorio-impiego-medicinali-osmed]

expenditure ceilings, including the revision of the budget allocation system to companies	systems for the management of the regulations concerning the respect of the expense ceilings and the pharmaceutical pay-back that give certainty of application to all the subjects involved, also in order to overcome the systematic recurrence of litigation.
q) Presence of ad hoc funds	Ad hoc funds can be useful in extraordinary conditions.
r) Reorganization of CTS-CPR operation	In order to avoid such diseconomies, it would be desirable to unify the two commissions and to foresee that a part of the commissions' activity be carried out jointly.
s) AIFA: Board of Directors, relations with the Regions and supervision by the competent Ministries	The opportunity to include a representative of the Minister of Economy and Finance among the members is noted.
t) Involvement of patient representatives	It is proposed to establish a permanent consultation table with the presence of representatives of patient associations.
u) National Coordination Centre of Ethics Committees based in AIFA	It is necessary to evaluate a different location of the Coordination Centre outside AIFA, a proposal that requires a specific regulatory intervention.
v) Relations with the Higher Institute of Health (HIH) and Agencies	There is a partial overlap that requires greater collaboration in order to exploit the existing synergies
w) Cipe resolution 2001	It is necessary to revise and update the contents of the 2001 CIPE resolution setting the criteria for negotiating the price of drugs, to take into account the evolution in the pharmaceutical sector

[Source: our elaboration on DOCUMENT ON THE SUBJECT OF PHARMACEUTICAL GOVERNANCE, 2018, pp.2-10]