

## Does EU Anti-Corruption Regulation Work: The Case of Pharmaceutical Industry

Alex Almici Ph.D.

Department of Economics and Management  
University of Brescia  
C.da S.Chiera, 50 25122 Brescia  
Italy

### Abstract

*Corruption in the pharmaceutical industry has become a hot topic, cause the increasing scandals recorded by worldwide media. Pharmaceutical sector is characterised by many vulnerabilities to corruption that can lead – in the worst case scenario – to human death. Policy-makers have a relevant role in combating corrupt practices, by introducing effective measures against this widespread phenomenon. This study aims at verifying the European regulation’s contribution in combating corruption occurring in the pharmaceutical sector; in this regard, the main results underline some limits of regulation as well as some strength factors. Limits mainly refer to: provisions’ low specificity; the frequent provisions ‘general content; the great focus on specific types of corruption by neglecting the other ones; the relevant presence of voluntary regulation implying potential risk of no-compliance. The most relevant strength factors relate to the preventive policy-makers approach and to the high feasibility of the main part of regulation’s measures..*

**Keywords:** corruption, pharmaceuticals, regulation

### 1. Introduction

According to the World Health Organization “essential medicines save lives and improve health when they are available, affordable, of assured quality and properly used” (WHO, 2004). Despite the importance of pharmaceuticals to health systems, evidence reveals that public sector availability of generic medicines is less than 60% across WHO regions, ranging from 32% in the Eastern Mediterranean Region to 58% in the European Region (WHO, 2011). However, this depends on a number of variables; one of them is identifiable in corruption. In this sense, there is mounting evidence of the negative effects of corruption on the health and welfare of citizens (McPake et al., 1999; Gupta et al.; 2002; Azfar, 2005; Lewis, 2006; Rose, 2006; Gandini et al, 2014). Corruption is a pervasive problem affecting, in general, the economic and social development and, in particular, the health sector; indeed, the European Commission estimates that €120 billion is lost to corruption each year throughout the 27 members states (EUobserver, 2013), while approximately 56 billion euro is lost annually to fraud and corruption in health sector (Gee, Button & Brooks, 2011). This phenomenon has become an hot topic in the pharmaceutical sector cause the increasing scandals regarding cases of corruption as underlined by worldwide media. Starting from the observation of the main scandals occurred in the pharmaceutical industry, the present study aims at answering to the following research question:

*Considering the pharmaceutical’s sector weaknesses and the related types of corruption practices, which is the European regulation’s contribution to prevent/combat corruption in this sector?*

A review of the international business literature suggests that existing studies have typically focused either on (a) the effects of corruption on economic growth (Husted, 1999; Mauro, 1995; Treisman, 2000; Paldam, 2001; Akhter, 2004; Gonzalez-Velasquez, 2004; Serra, 2006; Guetat, 2006), or on (b) the analysis of the causes of corruption (Shleifer & Vishny, 1993; Rose-Ackerman, 1997; Collier, 2002; Sandholtz & Gray, 2003; Park, 2003; Aggarwala & Goodell, 2009; Goldsmith, 2009) and on the related measurement (Lancaster & Montilola, 1997; Eigen, 2002; Svensson, 2005; Kaufman, Kraay & Mastruzzi, 2008). Only a few studies analyse the effect of corruption on the health sector (McPake et al, 1999; Gupta et al, 2002; Azfar, 2005; Lantham, 2001; Cohen et al, 2002; Salvioni et al., 2015; Almici, 2015).

Sparse attention has been given to the regulation's impact on the corruption and specifically to corrupt practices in the pharmaceutical sector. There is a lack of scholarly research, especially research that analyses the contribution of European regulation to reduce practices carried out according to unethical principles. This paper attempts to fill this gap and add to the existing research by examining the pharmaceutical's system vulnerabilities to corruption and analyzing what law makers are doing to contrast this increasing phenomenon. The objective is to: evaluate the main European regulation measures adopted – until now – to fight corrupt practices; identify how regulation could be improved to increase the system's resistance to corruption. The main findings reported in Section 4 underline that regulation should be improved in order to: combat European corruption in a more effective manner, as there are some regulation limiting factors that must overcome; obtain these results a content analysis of European regulation has been carried out.

To achieve the above goal, this paper is divided into five sections. The Section 1 is an introduction to the research, while in Section 2, the analysis is focused on: the pharmaceutical's industry characteristics; the main weaknesses to corruption; the specific corrupt practices occurring in the pharmaceutical sector. In Section 3, the research methodology is presented and in Section 4 the main findings are shown. The final section contains some concluding remarks taken from the results explained in Section 4.

## **2. Theoretical background**

### *2.1 The pharmaceutical industry: main features*

The pharmaceutical industry – including companies engaged in researching, developing, manufacturing and marketing drugs (International Trade Administration, 2010) – has a great economic significance in the European economy: it is a major employer and it combines a large production value with high levels of innovation (Kanavos et al; 2011). In particular, European pharmaceutical industry accounts for more than 3,818 companies, it employed approximately 700,000 million people in 2013 with a total market value – at ex factory prices – of € 163,000 million and a value of exports reaching more than €300,000 million in the same year (Table 1).

According to the European Classification of Economic Activities system (NACE Rev.2), stated by the European Commission and adopted in the EU Member States, the pharmaceutical industry (division 21 of NACE) refers to the manufacture of basic pharmaceutical products and pharmaceutical preparations; the last one, constitutes the largest subsector, with a share of 90% of the value added of the entire pharmaceutical sector (Eurostat, 2009). In general, pharmaceutical products (also called drugs, medicines, medications or medicinal products) can be defined as “any chemical substance intended for use in the medical diagnosis, cure, treatment, or prevention of disease” (European Parliament, 2004).

Unlike other goods and services, pharmaceutical products embody some unique characteristics such as: high relevance for human life, as a specific drug can be a matter of life or death; high technical content, so that patients need doctors' prescriptions in order to take drugs in a correct way.

Similarly, pharmaceutical industry is characterized by specific aspects compared to other sectors; the main characteristics are illustrated below.

#### *Asymmetry of information*

Information imbalances are common among different actors; for example, producers have the benefit of having much more information than users in terms of product functioning, cost structure, while the users are strongly dependent on the knowledge, expertise and information provided by producers.

#### *Agency relationship*

Patients are aware they don't feel well but they rely on health professionals to act as their agents in diagnosing and treating diseases; the principal-agent problem in health care asserts that providers, being the imperfect agents of patients, will act to maximize their profits at the expense of the patients' interests.

#### *Government's role*

In the pharmaceutical industry, Government has a significant role as it must secure health policy objectives: protecting public health; guaranteeing patent access to safe and effective medicines; improving the quality of care; ensuring that pharmaceutical expenditure does not become excessive so as to undermine these specific goals (European Observatory on Health Systems and Policies Series, 2004).

### *High barriers to entry*

The pharmaceutical sector suffers problems related to the failure of competition which is strictly linked to the existence of high barriers to entry that may be identified in: natural barriers (economies of scale and scope, sunk costs of investment, reputation effects); legal barriers (patents and market authorization and the related approval costs); competitive barriers (dominant parties with a strong position on the market).

### *The complexity of the medicine chain*

The “medicine chain” is extremely complex, often involving up to thirty different parties before the product reaches the end user, thus creating the opportunity of carrying out unethical behaviors.

Indeed, in order to provide to the patients all the drugs they need, many steps have to be carried out; in detail, the main stages are the following:

- manufacturing, indicating the process of production of pharmaceuticals according to standards of Good Manufacturing Practice (GMP) (WHO, 2003);
- Registration and marketing authorization: before a pharmaceutical can be marketed in the EU the pharmaceutical company has to apply for marketing authorization according to specific procedures. The process of market authorization is generally undertaken by a national drug agency, responsible for the evaluation of a drug’s safety, its efficacy against a specific disease, its possible side-effects;
- selection, aiming at ensuring that the most cost-effective and appropriate drugs for a population’s health are chosen and that this is done fairly and transparently through the use of impartial expert committees;
- procurement, that is the main interface between pharmaceuticals industry and healthcare suppliers with the goal of acquiring the needed quantity of drugs;
- distribution aiming at maintain a constant supply of drugs, keeping drugs in good conditions and minimizing drug losses due to spoilage and expiry;
- prescribing and dispensing involving the participation of physicians, pharmacists, nurses and other health-care providers who diagnose patients and identify what drugs a patient should consume to treat a specific disease.

### *High number of actors involved*

The process running from the pharmaceutical company to the patient implies a complex interrelationship among producers (pharmaceutical companies), healthcare providers (individual doctors, doctors’ associations, medical institutions, research institutes, individual opinion leaders), patients, insurance providers, reimbursement systems, regulators (Ministry of health, standard setting agencies, healthcare authority), marketing authorization committees (i.e. the European Medicines Agency, the Committee for Medical Products for Human Use, the Standing Committee on Medical Products for Human Use, etc.)(Ecorys, 2009).

All the above stated industry’s characteristics can create a ground vulnerable to corrupt practices; in the next paragraphs the attention is focused, firstly, on the main factors weakening pharmaceutical industry and, secondly, on the related types of corruption.

### *2.2 The main vulnerabilities to corruption*

The sheer scale of the market makes it a very attractive target for abuse and greed is often reported as a main cause of corruption. However there are also other reasons for the sector’s vulnerability which may be identified in specific factors strictly related to the pharmaceutical characteristics above analysed (Cohen J.C. et al, 2002). First, the pharmaceutical sector includes many stakeholders whose roles, responsibilities and accountability relationships are often not clearly defined; besides, the large number of actors has complex interrelations which are not completely verifiable. The relation between the medical industry and the research organisations is a very close one: the design and conduct of clinical trials often involve collaboration between the company and a for-profit contract research organization (CRO), with a potential economic influence of the pharmaceutical companies on the research process in order to obtain the desired results from the clinical trials. Indeed, research organizations depend on renewed contracts from their pharmaceutical clients for survival, while these contracts give the pharmaceutical company complete control over the research results and all forms of research dissemination. Generally, the influence is exercised through informal payments often disguised as padded fees or consulting contract (Gale, 2011; Acemoglu and Gietzmann, 1997; Rodwin and Abramson, 2012).

A similar situation occurs with reference to physicians that have relations with suppliers of pharmaceuticals through consultancy contracts, conference, etc., implying a potential influence (favouritism) of the procurement process.

The relationship among patient, doctor and pharmaceutical companies is relevant as well: on the one hand, patient generally must rely on the doctor's expertise due to the information asymmetry; on the other hand, doctors are very important for originator companies because they prescribe pharmaceuticals, implying a potential conflict of interest between the business objectives of the industry and the duty to prescribe the most appropriate pharmaceuticals.

Second, the medicine chain is very long so that it is difficult to standardise and monitor all the medicine chain's stages and, in particular, those relating to service provision and procurement (Radulescu et Al, 2008).

Third, there is a high degree of information asymmetry – on various levels – among medical professionals, patients and payers for health care such as government agencies and health insurers.

Fourth, unlike consumer markets for “regular goods”, where market supply and demand determine ‘the right price’, in the complex market of pharmaceuticals pricing is much more opaque.

Fifth, even if the pharmaceutical sector is highly regulated, more enforcement (even through legal sanctions) and stronger regulation are needed especially with reference to procurement process.

Sixth, as the payer is often not the same of the direct consumer of healthcare services, there is no immediate check on the actual provision of goods and services. In other words, the payer has no direct way of verifying that the service was provided and the customer has no way of knowing that the insurance provider has billed for a service that the consumer did not receive.

Seventh, in pharmaceutical sector conflict of interest policies are lacking or there is a poor implementation of them if policies are in place.

Eighth, pharmaceuticals are sophisticated products so that the degree of possible controls in procurement procedures and regulatory affairs is limited; it means that few people can judge offer technically. The problem is larger and more deeply embedded in those countries characterised by weak procurement regulations.

Ninth, market competition is limited as pharmaceuticals are patent protected after their introduction while heavily investments in R&D are needed.

### *2.3 The typical forms of corruption in pharmaceutical industry*

Corruption in the pharmaceutical sector occurs throughout all stages of the medicine chain before the pharmaceuticals reach the patient; however, authorization, selection and procurement are the most vulnerable areas to corruption (European Commission, 2013).

In general, considering the above stated weaknesses, corruption may take many forms mainly identifiable in:

- corruption in marketing authorization, occurring with reference to the practices that a pharmaceutical company has to carry out to market its products. This kind of corruption takes place, for example, in case of: paying government officials to register the drugs without the requisite information; delaying deliberately the registration of a pharmaceutical product to favor market conditions for another supplier; slowing down deliberately registration procedures to solicit payment from a supplier;
- procurement corruption: procurement identifies the complete process of acquiring pharmaceuticals and medical devices from producers, involving - as main actors - the pharmaceutical industry (the bidder) and the healthcare suppliers. This type of corruption may occur in all phases of the procurement process: pre-bidding (corruptive needs assessment, circumvention of tender procedures, tailored tendering); bidding (bribery and kickbacks during the bid evaluation; favoritism; collusion and/or market division in bidding); post bidding (false invoicing, changing contract agreements)(DiTella and Savedoff, 2001). Procurement corruption may consist in bribes to individuals (money, leisure and trips, favoring relatives, offering discounts, etc.) or to medical institution (money, conference participation, free supply of materials, research funding and other forms of monetary and non-monetary sponsorship);

- improper marketing relations: this type of corruption is related to the registration of pharmaceuticals, drug selection, direct or indirect promotion of drugs or medical devices. In general, improper marketing relations occur when a pharmaceutical company provides any type of gifts (money, leisure activities, etc.) to doctors or medical institutions in order to stimulate prescription of preferred drugs to patients, instead of another similar product that is offered by a competing company. In some specific cases, improper marketing relations may take place when pharmaceutical companies make efforts to influence medical service providers or regulators to include their products in the positive list of drugs that are reimbursed by public funds (positive list promotion) (Gale, 2011);
- bribery in medical services delivery, consisting of informal payments from patients to healthcare providers to obtain access to healthcare, preferential treatment (by skipping waiting list), better quality of healthcare, false sick leave statement;
- undue reimbursement claims, occurring when healthcare providers request reimbursement of unnecessary or not delivered treatments as well as in the case of use of maximum allowable reimbursement levels for less complicated cases (upcoming);
- fraud and embezzlement of pharmaceuticals including the sale – by healthcare providers – of public or prepaid medicines for private gain and the sale of counterfeit medicines.

With reference to the methods of corrupting, the most common are those implying bribes and kickbacks. The former consists of offering money or other advantages in order to get a result unavailable without the bribe; the latter occurs when a corrupt official receives share of the profits or other advantages after the project has been completed. Corruption may occur also by informal payments, consisting in payments to individual and institutional providers, in kind or in cash, that are made outside the official payment channels (i.e. the so-called “envelope” payments to physicians, the “under-the-table” payments to doctors, nurses and other medical staff to obtain drugs in a easy way) (Lewis, 2000, 2002) or through inducement by giving benefits in order to stimulate a preference to buy a product or to promote loyalty to a specific supplier.

#### *2.4 Research question*

Starting from the observation of the vulnerabilities of the pharmaceutical industry and the related corrupt practices as reported in the previous paragraphs, this study aims at verifying the regulation’s contribution to combat corruption by answering to the following research question:

*Considering the pharmaceutical’s sector weaknesses and the related types of corruption practices, which is the European regulation’s contribution to prevent/combat corruption in this sector?*

### **3. Methodology**

The above stated research question has been addressed on the basis of a content analysis of the regulation and on the international guidelines applicable in Europe, facing corruption in the pharmaceutical sector. In this regard, the expression “European regulation” used in the present study refers not only to recommendations and laws issued by European law-makers, but to the anti-corruption regulation applicable in Europe even if introduced by no-EU bodies (WHO, OECD, etc.). The analysis is concentrated on the guidelines and principles issued at European level creating a general framework for each EU member State.

With regard to the analyzed European and international regulation, it is possible to distinguish two main categories of measures to address corruption: generic anti-corruption regulation (non-healthcare specific); specific regulation aiming at preventing, controlling and combating corruption within the healthcare system (corruption in health-policies).

The first category (non-healthcare specific) includes:

1. World Trade Organisation’s Government Procurement Agreement (1996) (WTOGPA).

This is a legal binding agreement based on transparency, competition and good governance, aiming at opening up to international competition and conformity of the members. Therefore, the agreement seeks to reduce corruption and bad governance, by providing specific international standards on the criminalisation of corruption. Its principle objective is to open up procurement to international competition and, in this context; it requires its parties to ensure the conformity of their laws and regulations with WTO GPA obligations.

2. EU Convention on the Fight against Corruption involving Officials of the European Communities or Officials of Member States of the EU (1997) (EU-CFACO).

This Convention relates to acts of corruption involving officials of the European Communities or officials of the Member States in general, by establishing criminal liability for heads of businesses.

3. OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions (1997) (OECD-CCBFPO).

This is an international anti-bribery regime aimed at criminalising bribery of foreign public officials in international business transactions.

4. Council of Europe's Framework Decision on combating corruption in the private sector (2003) (EU-FDCCPS). The framework decision requires EU members to establish criminal offences in domestic legislation to criminalise active and passive corruption in the private sector.

5. Council of Europe's Civil Law Convention on Corruption (2003) (EU-CLVC).

This Convention aims at providing effective remedies for persons who have suffered damage as a result of acts of corruption, to enable them to defend their rights and interests, including the possibility of obtaining compensation for damage.

6. United Nation's Convention against Corruption (2005) (UNCAC).

This Convention covers the broadest range of corruption offences, including: the active and passive bribery of domestic and foreign public officials, obstruction of justice, illicit enrichment, and embezzlement. It also includes preventive measures, international co-operation, technical assistance and provisions on asset recovery.

7. Council of Europe's Criminal Law Convention on Corruption (2007) (EU – CLCC).

The Convention combats the active and passive bribery of domestic and foreign public officials, bribery in the private sector and trading in influence.

8. OECD's Principles for Integrity in Public Procurement (2009) (OECD – PIPP).

These principles aim at developing and implementing a policy framework for enhancing integrity in public procurement.

9. United Nations Office on Drugs and Crime's Guidebook on anti-corruption in public procurement and the management of public finances (2013) (UNGAC).

The Guidebook provides specific guidelines to implement an effective public procurement system based on transparency, competition and integrity.

10. European Directive 2014/24/EU on Public Procurement (2014) (EU – DPP).

The Directive indicates some measure to be adopted in order to fight corruption in public procurement.

The second category (corruption in health care) includes:

1. International Federation of Pharmaceutical Manufacturers & Associations' Code of Practice (2012) (IFPMA – CP).

The IFPMA' Code promotes the implementation of good practices by pharmaceutical companies respect to all the players involved in the medicine chain (health-care professionals, medical institutions, patient organizations, etc.).

2. United Nations – Fighting corruption in the health sector (2013) (UNFCHS)

This study is a review of corruption assessment tools and anti-corruption interventions relevant for the health sector.

3. World Health Organization's Framework for good governance in the pharmaceutical industry (2014) (WHO – FGG)

The document "Good Governance for Medicines: Model Framework" provides some guidelines to promote good governance in the pharmaceutical sector, by strengthening health systems and preventing corruption practices.

With regard to the above stated regulation, the attention is focused on the analysis of the following aspects: the identification, in the analysed provisions, of specific measures to reduce the effects of pharmaceutical's system vulnerabilities to corruption; the existence, in the analysed regulation, of effective measures to prevent/combate corrupt practices in the pharmaceutical sector; the legally binding extent of regulation; the regulation specificity in terms of health generic provisions and health generic ones; the law-makers' approach to corruption (preventive or combating approach); the feasibility of identified measures (high, medium or low).

#### **4. Results**

In order to address the research question, international regulations analysed to verify the presence of specific measures aimed at: firstly, reducing the weaknesses of pharmaceutical industry and, secondly, preventing and combating the related forms of corruption.

The most important provisions about corruption, included in the analysed regulation, are the following in a chronological order; to simplify the reporting process of the main findings, each provision is identified by an alphabetic letter.

**World Trade Organisation’s Government Procurement Agreement (1996) (WTOGPA)**

*“A procuring entity shall conduct covered procurement in a transparent and impartial manner that:*

- avoids conflicts of interest;*
- prevents corrupt practices” (Art.4), identified – in the following tables – by the letter A.*

**OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions (1997) (OECD-CCBFPO)**

*“The bribery of a foreign public official shall be punishable by effective, proportionate and dissuasive criminal penalties” (Art. 3), identified – in the following tables – by the letter B.*

**EU Convention on the Fight against Corruption involving Officials of the European Communities or Officials of Member States of the EU (1997) (EU-CFACO)**

*“For the purposes of this Convention, the deliberate action of an official, who, directly or through an intermediary, requests or receives advantages of any kind whatsoever, for himself or for a third party, or accepts a promise of such an advantage, to act or refrain from acting in accordance with his duty or in the exercise of his functions in breach of his official duties shall constitute passive corruption. (Art. 2)*

*For the purposes of this Convention, the deliberate action of whosoever promises or gives, directly or through an intermediary, an advantage of any kind whatsoever to an official for himself or for a third party for him to act or refrain from acting in accordance with his duty or in the exercise of his functions in breach of his official duties shall constitute active corruption” (Art. 3), identified – in the following tables – by the letter C.*

**Council of Europe’s Civil Law Convention on Corruption (2003) (EU-CLVC)**

*“Each Party shall provide in its internal law for appropriate protection against any unjustified sanction for employees who have reasonable grounds to suspect corruption and who report in good faith their suspicion to responsible persons or authorities” (Art. 9), identified – in the following tables – by the letter D.*

**Council of Europe’s Framework Decision on combating corruption in the private sector (2003) (EU-FDCCPS)**

*“Member States shall take the necessary measures to ensure that the following intentional conduct constitutes a criminal offence, when it is carried out in the course of business activities:*

- (a) promising, offering or giving, directly or through an intermediary, to a person who in any capacity directs or works for a private-sector entity an undue advantage of any kind, for that person or for a third party, in order that that person should perform or refrain from performing any act, in breach of that person's duties;*
- (b) directly or through an intermediary, requesting or receiving an undue advantage of any kind, or accepting the promise of such an advantage, for oneself or for a third party, while in any capacity directing or working for a private-sector entity, in order to perform or refrain from performing any act, in breach of one's duties” (Art. 2), identified – in the following tables – by the letter E.*

**United Nation’s Convention against Corruption (2005) (UNCAC)**

*“Each State Party shall, in accordance with the fundamental principles of its legal system, take the necessary steps to establish appropriate systems of procurement, based on transparency, competition and objective criteria in decision-making that are effective, inter alia, in preventing corruption. Such systems, which may take into account appropriate threshold values in their application, shall address, inter alia:*

- (a) The public distribution of information relating to procurement procedures and contracts, including information on invitations to tender and relevant or pertinent information on the award of contracts, allowing potential tenderers sufficient time to prepare and submit their tenders;*
- (b) The establishment, in advance, of conditions for participation, including selection and award criteria and tendering rules, and their publication;*
- (c) The use of objective and predetermined criteria for public procurement decisions, in order to facilitate the subsequent verification of the correct application of the rules or procedures;*
- (d) An effective system of domestic review, including an effective system of appeal, to ensure legal recourse and remedies in the event that the rules or procedures established pursuant to this paragraph are not followed;*

(e) Where appropriate, measures to regulate matters regarding personnel responsible for procurement, such as declaration of interest in particular public procurements, screening procedures and training requirements” (Art. 9), identified – in the following tables – by the letter **F**.

**Council of Europe’s Criminal Law Convention on Corruption (2007) (EU – CLCC)**

“Each Party shall adopt such legislative and other measures as may be necessary to establish as criminal offences under its domestic law, when committed intentionally in the course of business activity, the promising, offering or giving, directly or indirectly, of any undue advantage to any persons who direct or work for, in any capacity, private sector entities, for themselves or for anyone else, for them to act, or refrain from acting, in breach of their duties” (Art. 7), identified – in the following tables – by the letter **G**.

**OECD’s Principles for Integrity in Public Procurement (2009) (OECD – PIPP)**

**“A. Transparency**

1. Provide an adequate degree of transparency in the entire procurement cycle in order to promote fair and equitable treatment for potential suppliers.
2. Maximise transparency in competitive tendering and take precautionary measures to enhance integrity, in particular for exceptions to competitive tendering.

**B. Good management**

3. Ensure that public funds are used in procurement according to the purposes intended.
4. Ensure that procurement officials meet high professional standards of knowledge, skills and integrity.

**C. Prevention of misconduct, compliance and monitoring**

5. Put mechanisms in place to prevent risks to integrity in public procurement.
6. Encourage close co-operation between government and the private sector to maintain high standards of integrity, particularly in contract management.
7. Provide specific mechanisms to monitor public procurement as well as detect misconduct and apply sanctions accordingly.

**D. Accountability and control**

8. Establish a clear chain of responsibility together with effective control mechanisms.
9. Handle complaints from potential suppliers in a fair and timely manner.
10. Empower civil society organisations, media and the wider public to scrutinise public procurement” (p. 18-19), identified – in the following tables – by the letter **H**.

**International Federation of Pharmaceutical Manufacturers & Associations’ Code of Practice (2012) (IFPMA – CP).**

“ - Sponsorship to healthcare professionals is limited to the payment of travel, meals, accommodation and registration fees;

- No payments are made to compensate healthcare professionals for time spent in attending the Event; and any sponsorship provided to individual healthcare professionals must not be conditional upon an obligation to prescribe, recommend, purchase, supply, administer or promote any pharmaceutical product.

Companies should not pay any costs associated with individuals accompanying invited healthcare professionals. Health care professionals may be engaged as consultants and advisors for services such as speaking at and/or chairing meetings and events, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration. The arrangements which cover these genuine consultancies or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:

- a written contract or agreement must be agreed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis for payment of those services;
- a legitimate need for the services must be clearly identified and documented in advance;
- the criteria for selecting consultants must be directly related to the identified need and the consultants must have the expertise necessary to provide the service;
- the number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need;

- the hiring of the consultant to provide the relevant service must not be an inducement to prescribe, recommend, purchase, supply, and/or administer any medicine; and the compensation for the services must be reasonable and reflect the fair market value of the services provided”, identified – in the following tables – by the letter **I**.

Payments in cash or cash equivalents (such as gift certificates) must not be provided or offered to healthcare professionals. Gifts for the personal benefit of healthcare professionals (such as sporting or entertainment tickets, electronics items, etc.) must not be provided or offered” (p. 8-9), identified – in the following tables – by the letter **L**.

#### **United Nations – Fighting corruption in the health sector (2013) (UNFCHS)**

“Require that staff of regulatory agency and any supplemental committee members involved in registration and market approval decisions sign a conflict of interest document that is publicly disseminated.

Institute a body to manage conflicts of interest” (p. 30), identified – in the following tables – by the letter **M**.

“- Set up a well resourced independent drug agency.

- Ensure registration and marketing approval procedures are applied uniformly, are current for all suppliers, and are publicly available through a government website.

- Ensure that the regulatory agency publicly provides justification for decisions.

- Implement and sustain ongoing market surveillance of drugs with a complementary public education campaign to help educate consumers about how to identify a counterfeit product” (p. 29), identified – in the following tables – by the letter **N**.

“Ensure clear policy on quantification methodology for supplies.

Ensure that: closing date of all procurement bids is adhered to; all bids are recorded; all awards and adjudication decisions are made by the procurement committee or tender board.

Publish all procurement tender bids and results of contract awards online.

Use electronic bidding where possible.

Prequalify suppliers (e.g., through the WHO Prequalification Programme).

Monitor prices of supplies.

Check prices against international benchmarks.

Use international guidelines for health supply procurement practices.

Mandate regular reporting of key procurement performance indicators.

Commission expert committee with oversight over all procurement.

Provide technical assistance and training of procurement officers” (p. 72), identified – in the following tables – by the letter **O**.

#### **United Nations Office on Drugs and Crime’s Guidebook on anti-corruption in public procurement and the management of public finances (2013) (UNGAC)**

“Article 9 of UNCAC sets the general parameters for shaping national public procurement legislation. It requires establishing appropriate systems of procurement based on the fundamental principles of transparency, competition and objective criteria in decision-making. A good procurement system distinguishes itself, firstly, by incorporating these principles effectively and, secondly, by making sure that these principles are applied throughout the entire procurement process”(p.4), identified – in the following tables – by the letter **P**.

#### **European Directive 2014/24/EU on Public Procurement (2014) (EU – DPP)**

“Contracting authorities shall treat economic operators equally and without discrimination and shall act in a transparent and proportionate manner.

(...) Competition shall be considered to be artificially narrowed where the design of the procurement is made with the intention of unduly favouring or disadvantaging certain economic operators” (Art. 18), identified – in the following tables – by the letter **Q**.

#### **World Health Organization’s Framework for good governance in the pharmaceutical industry (2014) (WHO – FGG)**

“The model framework for good governance for medicines is intended to be a guideline and can be adapted by each country according to their needs. (...)

There are 10 basic components of the model framework (...)

Key ethical principles

Code of conduct

*Socialization of key ethical principles*

*Promoting ethical leadership*

*Enforcement of existing anti-corruption legislation*

*Mechanisms for whistle blowing*

*Sanctions on reprehensible acts based on anti-corruption legislation*

*Transparent and accountable regulations and administrative procedure*

*Collaboration among anti-corruption agencies, civil society organizations and the private sector*

*Management, coordination and evaluation” (p. 10), identified – in the following tables – by the letter **R**.*

The results relating to the contribution of European regulation to reduce the weaknesses to corruption of the pharmaceutical system are reported in Table 2.

Results reported in Table 2 underline how some specific vulnerabilities to corruption – such as asymmetry information and opacity in pricing definition – are not considered by European regulation, while with reference to the other aspects, some specific measures are introduced even if according to a generic approach rather than to a pharmaceutical specific one. The great focus of the regulation is on: the complexity of “medicine chain” and the interrelations among the different actors; the limited degree of controls in procurement process; the absence of immediate check of the actual provisions. Indeed, the presence of many stakeholders whose roles and responsibilities are often not clearly defined as well as the high length of medicine chain are relevant factors of vulnerability to corruption; so that, law makers concentrate their attention on these aspects and on the co-related effects (limited controls, corrupt practices in procurement process, etc.). In detail, the core of policies included in the regulation provisions mainly refer to: procurement activities that should be carried out according to transparency, competition and objective criteria in decision-making; registration and authorization procedures that should be applied uniformly by the involvement of independent drug agencies; the prohibition of offering money or gifts to healthcare professionals for their personal benefit.

In general, the main part of the above stated measures are legally binding, even if the recommended ones are therefore numerical relevant.

Table 3 shows the results about the measures introduced by regulation – both legally binding and applicable on voluntary basis– with reference to the specific type of corruption occurring in the pharmaceutical sector. Results reported in Table 3 underline that law-makers’ attention is mainly concentrated on the most frequent corrupt practices such as procurement corruption and improper marketing relations. Otherwise, sparse relevance is given to the other forms of corruption (bribery in medical services delivery, undue reimbursement claims, fraud and embezzlement of pharmaceuticals). In general, the regulation requires the implementation of procurement process and the promotion of pharmaceutical products according to transparency, integrity, good management, accountability and control. In this regard, the analysis of selected regulation underlines that, in some cases, the provisions are general and do not include any type of measure against corruption; so that, an improvement of regulation content is needed in order to provide an effective set of anti-corruption tools. The provisions are mainly compulsory but health-generic; only a few of them refer to the pharmaceutical sector specifically.

Findings in Table 4 underline the general regulation’s approach to corruption in terms of preventing/combating the phenomenon. With regard to this aspect, the analysis of the regulation shows a positive approach, as the main part of analysed provisions aims at preventing corruption, rather than defining measures to be applied when the corrupt practices have already been recorded.

Table 5 shows the expected feasibility of the regulation’s measures in terms of high, medium or low feasibility. Around 50% of the analysed provisions include measures highly feasible, such as: the use of electronic bidding and international guidelines for health supply procurement practices; the nomination of a commission expert committee with oversight over all procurement activities; the implementation of control procedures of supplies prices also by referring to international benchmarks. The remaining provisions include a three cases of measure’s low feasibility: the implementation of a procurement system incorporating the fundamental principles of transparency, competition and objective criteria in decision-making; the implementation of a good governance model based on specific components such as the promotion of ethical leadership, the mechanism for whistle blowing, etc.; the observance of a specific set of principles (transparency, good management, prevention of misconduct, compliance and monitoring, accountability and control) aiming at ensuring the integrity of procurement process. These three measures are considered to be low feasible as their implementation requires great efforts and resources by pharmaceutical’s companies.

## 5. Conclusions

Pharmaceutical sector is complex and characterised by much vulnerability to corruption which can lead – in the worst case scenario – to human death. Thus, corruption in the pharmaceutical sector cannot be ignored; in this regard, policy-makers need to know where the weaknesses lie, how serious these weaknesses are in terms of human impact and economic outcomes, prioritize and then define the appropriate anti-corruption strategies. In this study, the analysis is focused on the regulation's contribution – at a European level – to prevent/combat corrupt practices; the main findings may be distinguished between provision's limits and strength factors.

Provision's limits are the following:

1. EU anti-corruption regulation is mainly “health generic”; only a few documents refer specifically to the pharmaceutical sector. This is a potential limiting factor for the definition of effective anti-corruption policies in the pharmaceutical industry;
2. the analysed regulation focuses mainly on specific type of corruption such as procurement corruption and marketing improper relations, while the other typical cases (undue reimbursement claims, fraud and embezzlement of pharmaceuticals, bribery in medical services delivery) are, in general, neglected. In order, to address in an effective manner the problem of corruption, it should be useful to consider all the different kind of corrupt practices, including the less relevant as well;
3. EU anti-corruption regulation is mainly based on legally binding provisions, even if depending on the member States' implementation; however, voluntary regulation has a great relevance as well, implying a risk of ignoring the recommended practices at all;
4. in some cases, provisions do not indicate a specific measure to implement, but they only include general clauses without operating impact. In this regard, regulation should be more detailed in order to select the best strategy for each possible corrupt practice.

Strength factors are indicated as follows:

1. The general approach to corruption is based on prevention; this is a factor that may reduce the diffusion of corrupt practices if it is well-combined with the definition of effective measures;
2. The reported measures have a feasibility good level as around 50% of them record a high level of feasibility, increasing the effectiveness of defined strategies to combat corruption.

To address drivers of corruption prevailing in pharmaceutical sector, EU wide policies are needed in order to: set a clear and effectively enforced general anti-corruption rules; introduce independent and effective judicial follow up on corruption cases; implement sound and transparent general procurement systems.

In any case, it is clear that in order to have a significant impact on corruption, regulation has a great relevance, but it is not enough; to combat corruption in an effectively manner, it is necessary to combine a so-called “discipline approach” based on law-makers contributions, with a “value approach” promoting institutional integrity through the wide sharing of moral values and ethical principles (WHO, 2014).

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**Table 1 – The pharmaceutical industry in Europe (values in €million)**

Industry (Epfia total)	1990	2000	2012	2013
Production	63,010	125,301	213,003	217,500
Exports	23,180	90,935	312,377	316,500
Imports	16,113	68,841	224,811	226,500
Trade balance	7,067	22,094	87,566	90,000
R&D expenditure	7,766	17,849	30,035	30,630
Employment (units)	500,879	534,882	693,195	690,000
R&D employment (units)	76,126	88,397	115,196	115,000
Pharmaceutical market value at ex-factory prices	41,147	86,704	160,574	163,000
Pharmaceutical market value at retail prices	64,509	140,345	237,240	240,800

Source: European Federation of Pharmaceutical Industries and Associations, *The Pharmaceutical Industry in Figures, Brussels, 2014*

**Table 2 - European regulation and the pharmaceutical system's vulnerabilities to corruption**

Weaknesses to corruption	Source of regulation and binding extent	Measures	Regulation specificity
Complexity of interrelations among the pharmaceutical key-actors	OECD-CCBFPO – legally binding	<b>B</b>	Health generic
	EU-FDCCPS – legally binding	<b>E</b>	Health generic
	EU - CLCC – legally binding	<b>G</b>	Health generic
	EU-CFACO – legally binding	<b>C</b>	Health generic
	WHO – FGG – recommended	<b>R</b>	Health specific
High complexity and high length of medicine chain	OECD-CCBFPO – legally binding	<b>B</b>	Health generic
	OECD – PIPP - recommended	<b>H</b>	Health generic
	IFPMA – CP - recommended	<b>I</b>	Health specific
Asymmetry information	-	-	-
Opacity in pricing definition	-	-	-
Absence of immediate check of actual provisions	WTOGPA – legally binding	<b>A</b>	Health generic
	OECD – PIPP - recommended	<b>H</b>	Health generic
	UNFCHS – recommended	<b>O</b>	Health specific
Lack of conflict of interest policies	OECD-CCBFPO – legally binding	<b>B</b>	Health generic
	UNFCHS – recommended	<b>M</b>	Health specific
Limited degree of possible controls in procurement processes and regulatory affairs	WTOGPA – legally binding	<b>A</b>	Health generic
	EU-CLVC – legally binding	<b>D</b>	Health generic
	UNCAC – legally binding	<b>F</b>	Health generic
	UNGAC – recommended	<b>P</b>	Health generic
	EU DPP – legally binding	<b>Q</b>	Health generic
Limited market competition (patented products, high R&D, etc.)	UNFCHS – recommended	<b>N</b>	Health specific

**Table 3 - European regulation and the main corrupt practices**

Type of corruption	Source of regulation and binding extent	Measures	Regulation specificity
Corruption in marketing authorization	EU-CLVC – legally binding	<b>D</b>	Health generic
	UNFCHS - recommended	<b>N</b>	Health specific
Procurement corruption	WTOGPA – legally binding	<b>A</b>	Health generic
	EU-CLVC – legally binding	<b>D</b>	Health generic
	UNCAC – legally binding	<b>F</b>	Health generic
	CLCC – legally binding	<b>G</b>	Health generic
	OECD – PIPP – recommended	<b>H</b>	Health generic
	UNGAC – recommended	<b>P</b>	Health generic
	EU DPP – legally binding	<b>Q</b>	Health generic
Improper marketing relations	UNFCHS - recommended	<b>O</b>	Health specific
	EU-CFACO – legally binding	<b>C</b>	Health generic
	WHO – FGG – recommended	<b>R</b>	Health specific
	OECD-CCBFPO – legally binding	<b>B</b>	Health generic
	EU-FDCCPS – legally binding	<b>E</b>	Health generic
Bribery in medical services delivery	EU - CLCC – legally binding	<b>G</b>	Health generic
	IFPMA – CP - recommended	<b>I</b>	Health specific
	IFPMA – CP - recommended	<b>L</b>	Health specific
Undue reimbursement claims	EU-CLVC – legally binding	<b>D</b>	Health generic
Fraud and embezzlement of pharmaceuticals	-	-	-

**Table 4 - Regulation's general aim**

Source of regulation and binding extent	Measures	General aim	Regulation specificity
WTOGPA – legal binding	<b>A</b>	To prevent corruption	Health generic
OECD-CCBFPO – legal binding	<b>B</b>	To combat corruption	Health generic
EU-CFACO – legal binding	<b>C</b>	To combat corruption	Health generic
EU-CLVC – legal binding	<b>D</b>	To prevent corruption	Health generic
EU-FDCCPS – legal binding	<b>E</b>	To combat corruption	Health generic
UNCAC – legal binding	<b>F</b>	To prevent corruption	Health generic
EU – CLCC – legal binding	<b>G</b>	To combat corruption	Health generic
OECD – PIPP - recommended	<b>H</b>	To prevent corruption	Health generic
IFPMA – CP - recommended	<b>I - L</b>	To prevent corruption	Health specific
UNFCHS - recommended	<b>M – N – O</b>	To prevent corruption	Health specific
UNGAC - recommended	<b>P</b>	To prevent corruption	Health generic
EU – DPP – legal binding	<b>Q</b>	To prevent corruption	Health generic
WHO – FGG – recommended	<b>R</b>	To prevent corruption	Health specific

**Table 5 – Feasibility of regulation measures against corruption**

Types of corruption	Source of regulation and binding extent	Measures	Feasibility of the measure
Corruption in marketing authorization	EU-CLVC – legal binding	<b>D</b>	High
	UNFCHS – recommended	<b>N</b>	Medium
Procurement corruption	WTOGPA – legal binding	<b>A</b>	High
	EU-CLVC – legal binding	<b>D</b>	High
	UNCAC – legal binding	<b>F</b>	Medium
	CLCC – legal binding	<b>G</b>	High
	OECD – PIPP – recommended	<b>H</b>	Low
	UNGAC – recommended	<b>P</b>	Low
	EU DPP – legal binding	<b>Q</b>	High
	UNFCHS – recommended	<b>O</b>	Medium
Improper marketing relations	EU-CFACO – legal binding	<b>C</b>	Medium
	WHO – FGG – recommended	<b>R</b>	Low
	OECD-CCBFPO – legal binding	<b>B</b>	High
	EU-FDCCPS – legal binding	<b>E</b>	High
	EU - CLCC – legal binding	<b>G</b>	High
	IFPMA – CP – recommended	<b>I</b>	Medium
Bribery in medical services delivery	IFPMA – CP – recommended	<b>L</b>	Medium
Undue reimbursement claims	EU-CLVC – legal binding	<b>D</b>	High
Fraud and embezzlement of pharmaceuticals	-	-	-