



Study of Medicine E-Trade Regulation in Senegal

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Abstract

Introduction: E-trade covers, in addition to online selling activities, services relating to internet use. Several European states already authorize medicines e-trade, with or without prescription. In Senegal, fake drugs online sale in violation of pharmaceutical monopoly has provoked many debates, both among health professionals and patients. The objective of our work is to contribute to development of medicine e-trade regulation in Senegal.

Methodology: It's a retrospective and cross-sectional study, carried out from October 1st, 2018 to July 31th, 2019, using a documentary review and interviews. Data were compared with those of the literature.

Results: There is a significant institutional mechanism marked by establishment of structures and/or control of e-trade. At legal level, law on electronic transactions and its implementing decree encourage exercise of e-trade activity. Violations of rights of person with regard to processing of personal data are sanctioned. However, technical service provider has an obligation to inform consumer, who may apply withdrawal right, due to unavailability of goods or services ordered. As for drug trade, practice of pharmacy is well supervised. Monopoly of medicine sale is reserved for pharmacists, who must exercise their activity in a licensed pharmacy. However, medicines e-trade falling within same logic, and coming under full responsibility of pharmacist, is not taken into account by our current law on pharmacy. However, law on electronic transactions creates conditions for medicines e-trade exercise.

Conclusion: In Senegal, medicines e-trade does not have any specific regulations. However, law on e-trade has set up conditions for exercising medicine e-trade.

Keywords: Law; E-Trade; Electronic; Internet; Sale; Medicine; Regulation

Introduction

E-trade covers, in addition to online selling activities, services related to internet use [1]. Drugs sale is accessible via internet, and this activity is frequently made in violation of pharmaceutical monopoly [2]. In Europe, "Doc Morris" ruling laid down principles of medicines e-trade [3]. Several European states already authorize medicines sale with or without prescription on internet. It's a situation that

provokes many debates, both at level of health professionals and patients [4]. However, importance of counterfeit drugs sold on the Internet has led the WHO and the European Union to regulate drugs sale on Internet [5].

In Senegal, development of information and communication technologies [6] contributed to rise e-trade [7], which has experienced quick development, through speed and facilitation of economic transactions [8]. Thus,

new products more adapted to the needs of consumers needs have emerged [9]; in particular, medicines e-trade. In Senegal, drug monopoly belongs to pharmacists, and we do not have any specific medicines e-trade regulations. On one hand, it will be a question of making regulatory framework inventory for medicines e-trade, and on the other hand of relying on case law in this area, to propose a regulatory framework.

Purpose of Study

General Objective

- Contribute to the development of medicines e-trade regulation in Senegal.

Specific Objectives

- State legislative and regulatory framework for medicines e-trade;
- Make an inventory of drugs legislative and regulatory framework;
- Propose a regulatory framework for medicines e-trade, by interpreting case law on the subject.

Methodology

Type of Study

It's a retrospective and cross-sectional study that took place from October 1st, 2018 to July 31th, 2019.

Methodology

Data collection was first carried out by a review of legislative and regulatory texts on e-trade, followed by reading of chapter on "practice of pharmacy of Law 54-418 of April 15th, 1954". Finally, there were interviews with pharmacists.

Data analysis was done on one hand by exploiting the aforementioned data, to identify requirements relating to medicinal products e-trade; and on the other hand by comparing our texts with those of Europe, but also by exploiting the case law on the subject.

Results and Discussion

In Senegal, in absence of data specific to medicines e-trade, we made inventory of fixtures of e-trade and that of Book V on legislative part of pharmacy and medicines. Also, we have tried through case law, to identify perspectives to propose a framework regulating medicines e-trade.

About E-Trade

At institutional level, there is a system marked by key players, in particularly Ministry of Digital Economy and Telecommunications, Telecommunications and Posts Regulatory Agency, State Informatic and Technology Development Agency. They are supported by Personal Data Commission and national cybercrime office.

At the legal and regulatory level, e-trade is framed at Senegal by texts on electronic transactions, data protection and cybercrime.

Article 3 of decree on electronic transactions does not specify difference between direct e-trade and indirect e-trade [10]. For indirect e-trade we are interested in, delivery is made to your home or office, and only ordering and payment can be done online [8]. The definition does not shed light on marketing techniques on Internet, in particular "pull" technique (Internet user will visit merchant site and place an order) and "push" technique which consists of bringing offered by Internet user [11].

However, there are limits to e-trade, the freedom of which may be restricted for reasons of public security and public health [12].

Technical service provider (natural or legal person) has an information obligation. He must provide consumer with information relating to his surname and first name, or his company name, his address, and set out the applicable contractual conditions. In addition, he must mention on his merchant site, in a clear manner, total price of the product, a complete description of the service offered; also define terms of payment, and specify whether taxes and delivery costs are included. Anyone interested in an online offer must be able to check it, before confirming it by "double click" principle [13]. The author of the offer must acknowledge receipt of the order, and without undue delay electronically (by e-mail) of the order sent to him. The confirmations of acceptance as well as the acknowledgment of receipt are considered received when parties can access it [8].

When he is able to do so, electronic supplier must set up a service allowing the consumer to communicate directly with him. Proof of the existence of prior information, confirmation of said information, compliance with deadlines and consumer consent rests with the electronic supplier of goods or services [14].

Offer sent by a professional, must mention in accordance with article 12 of decree relating to e-trade the right to withdraw without giving any reason and without penalty

within a certain period. Withdrawal can be done on any medium allowing a written trace to be left and which can be kept for a long time but within seven working days. However, when the professional has not satisfied, deadline special information obligation studied above, is three months. Calculation of the period begins for services from the conclusion of the contract, and for products, from their receipt [15].

When the consumer exercises his right of withdrawal in disregard of above mentioned conditions, he is liable if damage arises from his behavior. The same applies to the direct costs of returning the ordered product, but only when the correct product has been delivered [16].

As for the professional, he is required to return free of charge and under the same payment conditions, within a period of fifteen days from the notification of the withdrawal, all sums received, except the price of the service actually provided and direct costs of dismissal. The refusal of an electronic supplier of goods or services to reimburse the amounts received from a consumer who exercises his right of withdrawal, is punishable by imprisonment and a fine of 200,000 francs to 2,000,000 francs or only one of these two penalties [17].

With regard to online advertising to public, it must not mislead the consumer about the offer made [18], nor encourage consumer to click on an advertising message. Advertising offenses are governed by Cybercrime Act.

In Senegal, contractual conditions applicable on a professional basis, by electronic means, must be specified [19]. At the level of international trade, the contract is subject to the law of seller or service provider. With the internet, consumer law of buyer's country should apply [20]. This would be a situation where a service provider would be faced with several customers from different countries. However, it could be resolved by harmonizing the regulations in the field in Senegal [21].

Moreover, when a contract is concluded electronically and relates to a sum equal to or greater than an amount fixed at 20,000 francs; professional contractor ensures the conservation of the writing which establishes it for a period of ten (10) years [22]. Retention period runs for the delivery of goods or immediate performance of the service, from the moment of the conclusion of the contract. In the event of delivery or deferred service, the period runs from the date of delivery or performance of the service.

On personal data protection, technical service providers must implement a technical system for storing information elements, and are subject to an obligation of result in terms

of data storage. Data stored relates exclusively to elements allowing identification of users of services provided by technical service providers [23]. They engage their responsibility by negligence. Also, service providers are bound by obligation of professional secret which may cease when the disclosure of personal identification elements has been made by concerned person [24].

As for Cybercrime, Infringements of person rights with regard to the processing of personal data, are punishable by imprisonment and fines. However, Cybercrime law has certain limitations [25]. Therefore, it is necessary to adapt the penal system to information and communication technologies.

About Medicines E-Trade

Pharmaceutical regulatory authority is responsible for ensuring compliance with conditions of practice of pharmacy, pharmaceutical monopoly, in particular medicines e-trade.

Medicinal products e-trade is an economic activity by which pharmacist offers or provides remotely and electronically, retail sale and medicinal products for human use dispensation to public, and for this purpose provides health information online [26].

In Senegal, Law 54-418 of April 15th, 1954 on Pharmacy Code does not take into account definition and regulatory requirements of medicines e-trade. This situation could be explained on one hand by the obsolescence of our law, and on other hand by the fact that it is a new activity in Africa.

However, law has advantage of having taken into account certain general provisions relating to drugs, pharmaceutical monopoly, general conditions for practicing profession of pharmacist and drugs advertising.

Regarding pharmaceutical monopoly, article L.512 of the law, specifies that medicines sale, including medicines e-trade, is reserved for pharmacists. Indeed, pharmaceutical monopoly prohibits non-pharmaceutical companies from engaging in medicines e-trade [27]. Profession of pharmacist is a function reserved for pharmaceutical companies which benefit from the monopoly [28]. In Senegal, this function is exercised by pharmacists registered at the College of pharmacy. Also, on practice of community pharmacy, any opening of a new pharmacy is subject to granting a license issued by the Minister of Health [29].

Court of Appeal authorizes community pharmacists to sell non-prescription drugs on internet. However, online ordering process should allow eye contact with pharmacist. This is a legal obligation imposed on dispensing pharmacist,

and taken into account by technology through its skype and whatsapp applications [30]. Also, Senegalese regulations require pharmacist to perform professional acts himself, or to supervise their execution if he does not perform them himself [31].

Regarding withdrawal right, it is not taken into account by Book V Pharmacy, and does not apply to drugs [15]. Indeed, retraction can only occur when consumer has the opportunity to try goods ordered or to use them without performance if the contract is instantaneous. Therefore, whenever the performance of the contract is done and it is impossible to test the thing ordered, withdrawal right disappears [15]. For contracts relating to medicines, which by their nature cannot be returned because they are likely to deteriorate or expire rapidly; this provision could be an advantage for medicines e-trade. In addition, withdrawal right may be applied when the professional is unable to perform his contractual obligations, due to unavailability of goods or services ordered [32].

For orders shipment, drug is either sent in a sealed packet under pharmacist responsibility; either patient (located near the pharmacy) goes to the pharmacy to take delivery of his order [33]. Article L.589 of Book V pharmacy stipulates that, "Any order delivered outside pharmacy can only be delivered in a sealed packet bearing customer's name and address".

About online payment, internet network (Wari, Orange Money, etc.) and bank cards (Visa, Electron) offer opportunity to pay easily; electronic invoicing is possible [34].

The security of exchanges is one of the major conditions for e-tradedevelopment. In France, e-trade activity is governed by the law of place of establishment [35]. In Senegal, it is the same case (aliena 3 of article 8 of the law on electronic transactions), except that it is up to the judge in the event of a contentious appeal, to set criteria for qualifying a permanent establishment and sustainable [36].

Also, Senegalese legislator [37] has specified that rules of private international law can in no case deprive consumer of his protection guaranteed by "the mandatory provisions (...) of Senegal relating to contractual obligations" [38].

As for medicinal products advertising, article L.551 provides that it is free with practitioners, must not be misleading and must comply with Marketing authoriation provisions.

However, Senegalese law is silent on acquisition of a virtual pharmacy website. In France, to have such a site, you must have a physical pharmacy, or be manager of a mutual or mining relief pharmacy [39]. Medicines e-trade to public

via Internet, is an operation reserved for sites backed by a pharmacy [40]. Medicines sale can only take place in a pharmacy, and under careful supervision of a pharmacist. In addition, pharmacist must declare his website to the National Commission for Computing and Liberties [41]. He is also responsible for data collected [20], which must be kept in databases guaranteeing confidentiality, integrity and relevance of information collected [42].

In Senegal, tools have been developed by Data Protection Commission, in particular forms for declaring the collection of personal data on a website, and for requesting an opinion on health data processing. There is also pharmacist's obligation of professional secret, violation of which is sanctioned by article L.363 of Senegalese Penal Code. Moreover, applicable law does not pronounce on medicines e-trade. However, contractual liability of electronic supplier of goods is automatically engaged in the event of non-performance of its obligations [43]. Obligation of result, which weighs on him, means that he is obliged to repair any damage, in particular consequences of his own shortcomings [44].

Pursuant to point 5 of article 3 of the aforementioned law, technical service providers are subject to a specific monitoring obligation in order to detect possible infringements.

Thus, they must allow users access to an abuse reporting form, allowing them to inform either service provider concerned or competent authorities of any manifestly illegal online content.

Conclusion

In Senegal, there are no specific regulations for medicines e-trade. However, activity is partly governed by law on electronic transactions which creates conditions for medicines e-trade emergence; and enables community pharmacists to benefit from a growth driver for their drug activities. Senegal should take opportunities offered by Law 54-418 of April 25th, 1954, and legislative and regulatory texts on electronic transactions, to develop medicines e-trade regulations.

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