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Healthcare risk management during the SARS-CoV-2 virus pandemic in the European Union: The guaranteed access to medicines

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Abstract.
BACKGROUND: The disease caused by the novel coronavirus SARS-CoV-2 has rapidly spread escalating the situation to an international pandemic. The absence of a vaccine or an efficient treatment with enough scientific evidence against the virus has generated a healthcare crisis of great magnitude. The precautionary principle justifies the selection of the recommended medicines, whose demand has increased dramatically.
METHODS: we carried out an analysis of the healthcare risk management and the main measures taken by the state healthcare authorities to a possible shortage of medicines in the most affected countries of the European Union: Spain, France, Italy and Germany.
RESULTS: the healthcare risk management in the European Union countries is carried out based on the precautionary principle, as we do not have enough scientific evidence to recommend a specific treatment against the new virus. Some measures aimed to guarantee the access to medicines for the population has been adopted in the most affected countries by the novel coronavirus.
CONCLUSIONS: in Spain, Italy and Germany, some rules based on the precautionary principle were pronounced in order to guarantee the supply of medicines, while in France, besides that, the competences of pharmacists in pharmacy offices have been extended to guarantee the access to medicines for the population.

Keywords: SARS-CoV-2, healthcare risk, medicines, supply, European Union

1. Introduction

At the end of 2019, a new type of virus of the *Coronaviridae* family was discovered, later called SARS-CoV-2. This virus was the cause of the respiratory disease known as COVID-19, whose main symptoms are coughing, fever, headache and, in more serious cases, breathing difficulties.

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This new virus has rapidly spread worldwide, affecting millions of people and causing a serious healthcare crisis, which has resulted in an international pandemic.[1] The main problem that poses is its high infection rate, being the close contact with respiratory secretions, generated when a sick person coughs or sneezes, its main form of transmission. Likewise, given its novelty, there is no vaccine or enough scientific evidence o any efficient medicine to fight against it. That's why the choice of measures adopted to deal with the said virus, are based on the precautionary principle.

The precautionary principle, which will be analyzed in the second section of this article, is the answer that the European law gives to scientific uncertainty situations, in a way that allows to manage the risk. This justifies the lack of scientific evidence regarding the risk management being carried out adequately, as it is the case of the pandemic at hand.

Besides, the high number of people suffering from COVID-19 has meant that these medicines that the healthcare authorities recommend as a treatment of choice, have dramatically increased their demand. This fact has compelled the authorities of every State to regulate the situation in order to guarantee the population's access to these medicines.

The European countries with more confirmed cases[2] are: Spain, France, Italy and Germany. Therefore, we will analyse the regulations enacted on the occasion of the healthcare crisis caused by COVID-19, aimed to guarantee the population's access to medicines [1].

2. Methods

We carried out a brief analysis of the precautionary principle, according to which the risk management measures were established during the pandemic caused by the novel coronavirus SARS-CoV-2 in the European Union. Furthermore, we analyzed the main measures enacted in order to guarantee the supply and the consequent population's access to medicines in the most affected countries by the crisis in the European Union: Spain, France, Italy and Germany.

3. Results

3.1. Risk management during the pandemic caused by the novel coronavirus SARS-CoV-2

A health risk is defined as the probability weighting of a detrimental effect on health and the severity of that effect as a result of a hazard factor [2]. Knowledge of these risks is often limited, as there are more or less wide margins of uncertainty about the causes, the effects and other risk factors. However, uncertainty is sometimes placed at the core, as is the case with the unprecedented health crisis caused by the new pathogen: SARS-CoV-2 virus.

[1] According to the World Health Organization, a pandemic is a worldwide spread of a new disease. In order to declare a pandemic, two criteria must be met: that the outbreak affects more than one continent and that the cases of each country are no longer imported but caused by community transmission. These conditions were met globally in early March 2020; and therefore, on 11th March 2020, the World Health Organization raised the healthcare situation to a global pandemic.

[2] The European countries with more confirmed cases as of August 2020 are: Spain (525,549), France (324,152), Italy (277,634) and Germany (250,779). Data obtained from the update no. 201 from the Coordination Center of Healthcare Emergencies and Alerts of the Spanish Government. Available at: https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov/documentos/Actualizacion_201_COVID-19.pdf.

In the face of these situations of scientific uncertainty, Community Law articulates its response around the so-called principle of caution or precautionary principle. It provides an ethical, political and legal response to the potentially dangerous situations of scientific uncertainty that we live in in our "society of risk" [3].

The origin of the principle of caution or precautionary principle is not clear but is usually traced to Germany. This principle was postulated within Environmental Law, closely connected to the idea of prevention.

The precautionary principle is reflected in different international conventions and declarations on the environment, with a particular impact on the 1992 Rio de Janeiro Conference. However, it is undoubtedly in the European Union Treaty that the precautionary principle finds its most important regulatory coverage [4].

The normative regulation of the precautionary principle is found in article 191 of the *Treaty on the Functioning of the European Union*.[3] The article states that, in situations of uncertainty where serious health risks arise, the Administration has the power to take measures aimed at safeguarding it, which may even be exceptional.[4]

In the context of the current pandemic, the absence of a vaccine or a specific treatment against the new virus, as well as the absence of scientific evidence in the decision-making and risk management processes, places the uncertainty at the core. This is an unprecedented pandemic, before which the European law applies the precautionary principle.

The risk management approach through the precautionary principle allows adopting measures in the event of a possible danger to human, animal or plant health, or to protect the environment even though there is not enough scientific evidence. This justifies some measures taken by the authorities, as the ones that will be analyzed below on the supply of medicines to guarantee the population's access to them.

It should be noted that the scale of this health crisis is due to the lack of specific treatment or vaccine against the new virus.

Each member country has produced a document on the treatments available for the management of respiratory infection with SARS-CoV-2, in which the available medicines are updated according to the evolution of research. Although numerous clinical trials are underway, there is currently no evidence to recommend specific treatment for SARS-CoV-2 [5]. Medicines recommended by health authorities include, for example, chloroquine/hydroxychloroquine. It is an active substance that is commonly used as a treatment against malaria and autoimmune diseases such as systemic lupus erythematosus or rheumatoid arthritis, because of its ability to act as an immunomodulator. There are no published clinical trials with either, although in vitro data and a review on the role of chloroquine in managing SARS-CoV-2 infection do [6]. Chloroquine appears to be effective in limiting the replication of SARS-CoV-2 in vitro [5]. Its effectiveness is being evaluated in a number of clinical trials. As there is no scientific evidence of any other effective treatment, its inclusion in the documents of the health authorities is justified by the situation of health crisis.

[3]Former Article 174 of the European Community Treaty.

[4]The precautionary principle is analyzed by Esteve Pardo on multiple occasions. See among others: Esteve Pardo, José [3]. *El desconcierto del Leviatán. Política y derecho ante las incertidumbres de la ciencia*. Madrid: Marcial Pons or Esteve Pardo, José [4]. "*La intervención administrativa en situaciones de incertidumbre científica. El principio de precaución en materia ambiental*" in: Esteve Pardo, Emilio. *Derecho del Medio Ambiente y Administración Local*. Madrid: Ed. Fundación Democracia y Gobierno Local.

Therefore, medicines containing the active substance chloroquine/hydroxychloroquine have undergone a large increase in their demand. The same has been the case with other medicines or medical devices that are recommended by health authorities as treatment for disease management, or those health products that are recommended for disease containment. For this reason, health authorities have begun to regulate their supply during the health crisis situation "based on the precautionary or precautionary principle which postulates that, the lack of decisive evidence is not a reason to refuse to regulate" [7], that is, the precautionary principle is articulated as a tool to regulate regulations without scientific evidence and as a prevention. This situation has led to increased demand for medicines used to alleviate symptoms caused by the disease. This has resulted in the authorities of the Community countries most affected by this health crisis having had to regulate their supply in an extraordinary way, in order to ensure their access to the population, as will be developed in the next paragraph of this article.

The high number of infected people who need treatment has led to an increase in the demand for the medicines used to alleviate the symptoms caused by the disease. This fact has led the authorities of the most affected countries by this crisis in the European Union to regulate, in an extraordinary way, the supply of medicines, in order to guarantee their access to the population, as we will explain in the next section of this article.

3.2. Guarantee of access to medicines during the pandemic in the most affected countries by the SARS-CoV-2 of the European Union

Every Member State has adopted its own measures to ensure access to medicines. Next, we will analyze the main actions carried out by the State healthcare authorities of the Member States more affected by the healthcare crisis: Spain, France, Italy and Germany.

3.2.1. Spain

In Spain, article 3.1 of the *Spanish Royal Decree 1/2015, on guarantees and rational use of medicines and healthcare products* [8] establishes the obligation for supplying medicinal and healthcare products to pharmaceutical laboratories (Marketing Authorisation Holder), distribution entities (wholesalers), importers, pharmacies, hospital pharmacy services, healthcare centers and other healthcare structures.

Noteworthy is article 3.3 of the *Spanish Royal Decree 1/2015, on guarantees and rational use of medicines and healthcare products*, according to which the Government is ultimately responsible for the supply of medicines and, therefore, may take special measures on all the links of the medicines legal supply chain, that is, from pharmaceutical laboratories, distribution entities, pharmacies and other healthcare structures [8].

However, in the face of the health crisis, the Government, through the promulgation of the *Royal Decree-Law 6/2020, of March 10, for the adoption of certain urgent measures in the economic field and for the protection of public health* [9] which amended the article 4 of the *Organic Law 3/1986, of April 14, on Special Measures in Public Health Matters* on its fourth article, has determined that the State Healthcare Administration will be the relevant authority to establish centralized supply and limit their prescription if a medicine or healthcare product is affected by exceptional supply difficulties.

Based on this, the Minister of Health, Consumer Affairs and Social Welfare issues the *Order SND/276/2020, of March 23, which establishes obligations of information supply, procurement and manufacture of certain medicines in the situation of health crisis caused by COVID-19* [10], where firstly, the capacity to prioritize the manufacture of the medicines necessary for the management of the health

crisis is regulated, and secondly, the Spanish Agency of Medicinal and Healthcare Products is appointed as the relevant authority to collect information on the planned manufacturing operations.

Therefore, making effective the first of the provisions, the minister with competence in health is in charge of establishing the obligation to guarantee the procurement of medicines considered essential for the protection of public health. This is done by including an appendix in the aforementioned Ministerial Decree that contains the main medicines that are considered essential for the management of the health crisis, and that will be updated according to its evolution.

The relevant health authority may order the prioritization of the manufacture of these medicines considered necessary for the protection of public health. Likewise, the Spanish Agency for Medicines and Healthcare Products may collect information on the planned manufacturing operations from the medicines manufacturers.

In addition, article 3 of the aforementioned Ministerial Decree establishes the obligation for the holder of the marketing authorization[5] to communicate electronically on a daily basis the available stock, the quantity supplied in the last twenty-four hours and the forecast of batch release and reception (dates and quantities) through the mechanism established by the Spanish Agency for Medicines and Healthcare Products, giving effect to the second of the provisions.

The role of the Spanish Agency of Medicinal and Healthcare Products stands out, having a double objective: to manage the stock of those medicines most affected by the health crisis in Spain and to facilitate their authorization during the pandemic period.

With respect to the first of the objectives, the Spanish Agency of Medicinal and Healthcare Products has controlled all the medicines that contain hydroxychloroquine, a medicine that is under study against SARS-CoV-2, and that is mainly used in patients with chronic diseases, such as lupus or rheumatoid arthritis due to its immunomodulatory potential. An informative note was issued stating that the holders of the authorization for marketing medicines that contain this active substance will inform the Agency about the stocks and will make them available to the relevant authorities of the Spanish Regions. Based on the actual number of patients/month ratio in this situation, the Agency will insure the monthly treatment stock once the stock now available in the channel is sold out. The Spanish Regions will arbitrate the control system to guarantee that this stock reaches the chronic patients who are out of hospitals [11]. Treatments will be prioritized for chronic patients and for clinical trials of all kinds that include hydroxychloroquine or chloroquine among their treatments, and for the treatment of patients admitted with pneumonia.

The second objective aims to facilitate the management of authorizations and modifications of authorization and registration of essential medicines for human use during the COVID-19 pandemic to guarantee the availability of medicines and thus avoid any supply issues.

3.2.2. France

In the French legislation, article L5121-29 of the *Public health code* [12], establishes that "*the holders of the marketing authorizations and the pharmaceutical companies must guarantee an adequate and continuous supply of the national medicines market in order to cover the needs of patients in France*".

Once the healthcare emergency was declared in the country, with the aim to guarantee the population's access to medicines, the "*Order of 14th March 2020 on different measures to fight the spread of the virus*

[5]According to the Spanish Agency of Medicinal and Healthcare Products, the holder of the marketing authorization is the natural or legal person responsible for the marketing of the medicine for which he has obtained the required marketing authorization.

of the COVID-19" [13], was enacted, which, in its fourth chapter deals with the measures regarding the community pharmacies. Article 6 of the said order increases the competences of the pharmacist in a way that, on an exceptional basis, when a renewable medical prescription expires, the pharmacist can continue to dispense it to guarantee the continuity of the treatment.[6]

Likewise, during the pandemic caused by the SARS-CoV-2 virus, the "*Law number 2020-290 of 23rd March 2020*" [14], was enacted, whose article 2 modifies the "*Public health code*". Regarding the question at hand, it modifies article L3131-1, authorizing the minister with health competences, in case of serious health threat requiring emergency measures, specially in case of epidemic threat, to adopt any measure, in proportion to the risks, and in the interest of the public health to prevent and limit the consequences of possible threats to the health of the population. It also modifies article L3131-15, in a way that, in the different territories where the state of healthcare emergency is declared, the Prime Minister will be able, through a regulatory decree along with the minister with health competences, to take all the necessary measures to make available patients the appropriate medicines to eradicate the healthcare emergency.

Besides, article 12.4 of the said law frees the healthcare professionals and the manufacturer of the medicines from the responsibility for the damages resulting from the prescription or administration of a medicine outside the therapeutic indications or normal use conditions provided by its marketing authorization or its temporary use authorization, or a medicine not subject to any of these authorizations, when its intervention was necessary due to the existence of a serious health threat and where the prescription or administration of the medicine was recommended or required by the Ministry of Health.

In this same line, the "*Order of 23rd March 2020, establishing the organization and operation measures of the healthcare system that are necessary to fight against the healthcare emergency of the COVID-19*" [15] was enacted, whose article 4 establishes that, given the healthcare situation, a series of guidelines between the pharmacist and the prescribing physician were created, in order to guarantee the continuity of chronic treatments. All of them increase the competences of pharmacists of the French pharmacy offices, for example, it is established that, "when the validity period of a renewable prescription expires, and with the aim of avoiding any treatment interruption that would damage the patient's health, pharmacies could dispense, in the context of the initially planned dosage, the necessary medication in order to guarantee the continuity of the treatment".[7] In that same article it is also set forth that "when a patient is not able to move to get a medicine for hospital use, it will be dispensed in the nearest pharmacy office to the patient's domicile". Furthermore, "pharmacists could renew, in the context of the initially planned dosage, the dispensation of medicines that contain substances with hypnotic or anxiolytic properties, provided that those medicines have been dispensed to the patient during at least three consecutive months".[8]

3.2.3. Italy

In Italy, the "*Law of 23rd December 1978, no. 833 on the establishment of the national health service*" in its article 29 regarding medicines, establishes that the production and distribution of medicines should

[6]The pharmacist is qualified to dispense a number of medicine boxes that guarantee the continuity of the treatment until the 31st May 2020. Narcotics or medicines to which the rules on narcotics are totally or partially applied, according to the said Order of 5th February 2008, will be excluded from the application scope of the article under study.

[7]The delivery for a period longer than a month, could not be guaranteed. It would be renewable until the 15th April 2020. The pharmacist will inform the physician. In the order should appear the stamp of the pharmacy, the date of issuance and the number of boxes delivered.

[8]The delivery for a period longer than 28 days, could not be guaranteed. It would be renewable until the 15th April 2020.

be regulated in order to guarantee the access to medicines for all the population [16]. Besides, the *Italian Republic Constitution* in its article 77 authorizes the government to dictate provisional measures with force of law in extraordinary cases of need and emergency [17].

Therefore, in order to guarantee an adequate management and containment of the healthcare crisis, in article 122 of the "*Law number 27, of 24th April 2020. Conversion into Law, with amendments, of the Decree-Law number 18, of 17th March 2020, that includes measures to reinforce the National Health Service and give economic support to families, workers and companies linked to the epidemiological emergency of COVID-19*" [18], a Special Commission for the application and coordination of containment measures and for the application of the law of epidemiological emergency, was designated. The same article establishes that this Commission will supervise, among others, the distribution processes of medicines, equipment and other medical devices for individual protection, in order to guarantee the access to medicines and, thus, face the national emergency regarding COVID-19. According to the authority granted to the Special Commission, it dictates a series of orders to seize all medicines and healthcare products considered as essential for the management of this healthcare crisis in Italy, forbidding their exportation as well.

On its part, we highlight the role of the Italian Agency of Medicines as, due to the unexpected increase in the demand of medicines used in treatments to fight the epidemic, shortages were generated, against which, apart from issuing the regular importation authorizations, this agency is collaborating with other pharmaceutical companies looking for exceptional and emergency solutions to guarantee their supply. Furthermore, the agency keeps a constant contact with the regions and autonomous communities, and they inform the agency on the medicines that are in a shortage situation [19].

At the same time, the Italian Agency of Medicines provides updated information about medicines used in clinical trials or about those that are marketed for other indications but that might be used against COVID-19, although their scientific evidence presents a high level of uncertainty, as we addressed in section two of this article [20].

3.2.4. Germany

In the German legislation, the "*Arzneimittelgesetz*", is the law that regulates the legal regime of medicines. On its article 52 b, section 1, establishes the duty of the Marketing Authorisation Holders and medicines providers to guarantee an adequate and continuous supply of medicines, so that the needs of patients are covered. In the same way, article 52 b, section 3 d, of the same law, designates the competent higher federal authority to take the necessary measures to guarantee the supply of a medicine in exceptional cases [21]. Besides, in the context of epidemiological crisis the law of protection against infections ("*Infektionsschutzgesetz*"), in its article 5, section 3, authorizes the Federal Minister of Health, without prejudice to the competences of the federal states, to adopt measures in order to guarantee the medicines supply, including vaccines and narcotics, medical devices, etc. [22].

Recently, because of the healthcare crisis caused by the SARS-CoV-2, the "*Law of protection of the population in case of a nation-wide epidemic*", which modifies the "*Infektionsschutzgesetz*", the law of protection against infections, in its section 5, establishes that, in the context of a nation-wide epidemic situation, the Federal Minister of Health is authorized to adopt measures with simplified procedures, without the approval of the Federal Council and with an emergency nature, to guarantee the supply of medicines and healthcare products [23]. For this reason, in April 2020 in some regions of Germany, specific regulations to guarantee the access to high-demand medicines during the healthcare crisis caused by the COVID-19 were published, as it is the case of those medicines whose active substance is hydroxychloroquine [24].

Furthermore, the Federal Institute of Medicines and Medical Devices, along with the European Commission, and the legal representatives of the Medicines Agencies of the Member States, through their Coordination Group for Mutual Recognition and Decentralised Procedures-Human (CMDh), agreed a number of measures aimed at facilitating the management of authorizations and modifications of medicines for human use considered essential during this pandemic period. These measures promote regulatory flexibility, facilitating, simplifying and speeding up administrative procedures aimed at avoiding any supply issues.

4. Conclusions

The coronavirus SARS-CoV-2 has caused an international pandemic before which the community healthcare authorities have had to manage the risks derived from it, on the basis of the precautionary principle.

The precautionary or precautionary principle constitutes a general legal support justifying the use of the forecast measures that have been developed in this article. This health crisis is characterized by uncertainty and lack of scientific evidence for virus containment and public health protection. This is an overview in which both the normative production and the absence thereof can have serious consequences. Therefore, the lack of scientific evidence does not find a reason not to regulate areas such as the one at hand, the provision of the supply of pharmaceutical products. The precautionary principle justifies measures taken regardless of their adequacy, always within reasonable limits and without incurring arbitrary measures. Recourse to the precautionary principle, in this case, is justified by two reasons. The first is because in the context of a pandemic the effects are not immediate, it is necessary to prevent in the field under study since the consequences of not being normative would be very serious. The second reason is that if the damage had been expected to occur, chances are that this damage caused could not have been restored. In the event that the supply of pharmaceutical products has not been extraordinarily regulated, there could have been a serious situation of shortage of medicines and medical devices in which protection is not guaranteed a basic right of persons such as the right to health, since it includes access to medicines and medical devices. The health authorities have therefore anticipated the health risk that may have arisen from a shortage in the context of this health crisis, ensuring the protection of the health of both those who are infected by the new coronavirus and those who may be collaterally affected. Therefore, the authorities have jurisdiction to anticipate the consequences and to use the precautionary principle to provide legal coverage to the measures described in the field of access to medicinal products.

The guarantee of access to medicines for the population is a common rule in all the legal systems we analyzed. Nevertheless, focusing on the main measures enacted during the healthcare crisis, aimed to guarantee the population's access to medicines, we observe that, on the part of the state authorities of Spain, Italy and Germany, theses have been mainly oriented to guarantee the supply of essential medicines. However, in France, apart from the guarantee the supply of medicines, they also increased the competences of the pharmacists in pharmacy offices. This has been carried out through some guidelines, including allowing pharmacists to dispense medicines for chronic treatments in their pharmacy offices, even though the prescription expired.

Conflict of interest

None to report.

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