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JUSTICE, TRADE, SECURITY, AND INDIVIDUAL FREEDOMS IN THE DIGITAL SOCIETY

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Chapter 5

The legal-administrative regime of medicinal products in the digital society era: challenges and opportunities from a spanish perspective*

Francisco Miguel Bombillar Sáenz

SUMMARY: I. MEDICINAL PRODUCTS IN THE DIGITAL SOCIETY ERA. II. ELECTRONIC MEDICAL PRESCRIPTIONS. PURCHASE OF MEDICINAL PRODUCTS THROUGH THE INTERNET (E-PHARMACIES). DISPENSATION OF MEDICINAL PRODUCTS USING RIDERS. DISPENSATION OF MEDICINAL PRODUCTS USING DRONES. USE OF BIG DATA IN CLINICAL TRIALS WITH MEDICINAL PRODUCTS. VII. FINAL THOUGHTS BY WAY OF CONCLUSION. VIII. BIBLIOGRAPHY.

I. MEDICINAL PRODUCTS IN THE DIGITAL SOCIETY ERA

A medicinal product is not a simple consumption product that is subject to the laws of the market – it is a health good subject to administrative

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intervention (Bombillar Sáenz,[1] Doménech Pascual,[2] González Bueno and Del Castillo Rodríguez,[3] Sarrato Martínez,[4] Vida Fernández,[5] among others) across all the stages of its *life* (invention, manufacturing, distribution, prescription, and dispensation). Medicinal products operate within a field of scientific uncertainty, in the context of what is called the *risk society* (Beck[6] and Esteve Pardo[7]).

As a consequence, the research (Antúnez Estévez[8]), production, and manufacturing of medicinal products remain under the supervision and control of the competent authorities, as well as their distribution, storage, prescription, and financing,[9] where appropriate, under the Public Health System,[10] and their dispensation by specific qualified and authorized professionals – the pharmacists (Villalba Pérez[11]).

The wide administrative intervention on medicinal products is led by the regulation and the decisions of the European institutions, executed, in a collaborative work network, by the different national authorities of medicinal products, becoming one of the greatest examples of policies in terms of public health (Cierco Seira[12]) undertaken by the European Union (Valverde López[13]).

1. For an overview of this sector, I refer to my two PhD theses on this topic: *Intervención administrativa y régimen jurídico del medicamento en la Unión Europea* (dir. Rafael Barranco Vela), Universidad de Granada, Granada, 2010, and *Regime giuridico del farmaco negli ordinamenti italiano e spagnolo: la trasposizione del diritto farmaceutico europeo* (dir. Marco Dugato), Università di Bologna, Bologna, 2010.
2. Gabriel Doménech Pascual, *Régimen jurídico de la farmacovigilancia* (Thomson-Aranzadi 2009).
3. Antonio González Bueno and Carlos Del Castillo Rodríguez, *Manual de Legislación Farmacéutica* (Dykinson 2019).
4. Luis Sarrato Martínez, *Régimen jurídico-administrativo del medicamento* (La Ley 2015).
5. José Vida Fernández, *Concepto y régimen jurídico de los medicamentos* (Tirant lo Blanch 2015).
6. Ulrich Beck, *La sociedad del riesgo global* (Siglo XXI 2002).
7. José Esteve Pardo, *El desconcierto del Leviatán. Política y derecho ante las incertidumbres de la ciencia* (Marcial Pons 2009).
8. Fernando Antúnez Estévez, 'Los ensayos clínicos' in Pilar Rivas Vallejo and María Dolores García Valverde (eds.), *Derecho y Medicina. Cuestiones jurídicas para profesionales de la salud* (Thomson-Aranzadi 2009).
9. Object of study, among others, by Rosa Basante Pol and Carlos del Castillo Rodríguez, 'Financiación de medicamentos: los aspectos jurídicos' (2013) 79(2) Anales RANF 293 et seq.
10. Registering access problems like the ones detected by Garrido Cuenca in the rare diseases field: Nuria Garrido Cuenca, *Derecho, salud pública y prestaciones sanitarias: retos éticos y jurídicos de las enfermedades raras* (Tecnos 2019).
11. Francisca Villalba Pérez, *La profesión farmacéutica* (Marcial Pons 1997).
12. César Cierco Seira, 'Emergencias de salud pública y medicamentos' (2017) 184 REDA 148 et seq.
13. José Luis Valverde López, 'El estatuto jurídico del medicamento' in Ministerio de Sanidad y Consumo (ed.), *España y Europa, hacia un ideal sanitario común. Recopilación*

Today, the health system revolves around the patient. Public health has lost its scepter, the quality of being essential. However, the study of this collective aspect should not be neglected (with fields such as epidemiological surveillance, animal health, environmental health, mortuary health, occupational health, food safety, or pharmacovigilance) because, as the different health crises experienced over the last few years at European and international levels have shown (*mad cow* disease, swine flu,[14] or COVID-19), we cyclically face serious threats where the states must coordinate their efforts to safeguard our collective health, managing the appropriate ablative measures to that end.[15] Without a doubt, the intervention of the competent authorities is still required in a police-like way, and this has been more than endorsed during the COVID-19 crisis.[16]

At the European level (Chowdhury,[17] Feldschreiber,[18] Krapohl[19] or Salvatore[20]), nowadays the two most important regulations in the

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comentada de textos comunitarios y nacionales en materia de Sanidad y Salud Pública (Ministerio de Sanidad y Consumo 2002).

14. Regarding the swine flu pandemic and the management of its vaccine by the European and Spanish health authorities, I refer to my article: 'The Case of Pandemic Flu Vaccines: Some Lessons Learned' (2010) 4 EJRR 429 et seq.

15. Since time immemorial, states have acted in the field of public health with the aim of fighting deadly epidemics and safeguarding our collective health [e.g., as in the Old Testament (*Leviticus* 13: 45-46 or *Numbers* 5: 1-3)] [César Cierco Seira, *Administración Pública y Salud colectiva. El marco jurídico de la protección frente a las epidemias y otros riesgos sanitarios* (Comares 2006)].

    However, public health, overthrown from its throne years ago by the healthcare side, is no longer only concerned with developing a repressive domain marked by the use of ablative measures such as quarantines, confinements, lazarets, or forced vaccinations. It is time for health promotion, to build health through measures focused on promoting healthy lifestyle habits among the population, such as promoting the practice of daily and moderate physical activity or the acquisition of good eating habits.

16. The object of my work '*Salus publica suprema lex est*: Intervención administrativa y gestión de la crisis del COVID-19' in Elena Atienza Macías and Juan Francisco Rodríguez Ayuso (dirs.), *Las respuestas del Derecho a las crisis de salud pública* (Dykinson 2020).

17. Nupur Chowdhury (ed.), *European Regulation of Medical Devices and Pharmaceuticals. Regulatee Expectations of Legal Certainty* (Springer International Publishing 2014).

18. Feldschreiber analyzes, in a classic work on this field, the structure and function of medicines regulation in the EU and UK. Peter Feldschreiber, *The Law and Regulation of Medicines* (Oxford University Press 2008).

19. Sebastian Krapohl, *Risk Regulation in the Single Market. The Governance of Pharmaceuticals and Foodstuffs in the European Union* (Palgrave Macmillan 2008).

20. Among other works, I highlight this chapter from the former head of the legal services of the European Medicines Agency: Vicenzo Salvatore, 'Qualità e sicurezza dei farmaci nel mercato interno dell'Unione europea' in Laura Pineschi (ed.), *La tutela della salute nel diritto internazionale ed europeo tra interessi globali e interessi particolari* (Editoriale Scientifica 2017).

pharmaceutical field are Directive 2001/83/CE of the European Parliament and of the Council, of 6 November 2001,[21] on the Community code relating to medicinal products for human use[22] and Regulation (EC) No 726/2004, laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and setting up the European Medicines Agency.[23]

This chapter analyzes the legal framework regulating medicinal products (especially in the stages of research, prescription, and dispensation) in the digital society era. Specifically, this work focuses on four problems, connected to each other but differentiated: 1) the prescription of medicinal products through electronic medical prescription (or e-prescription), 2) the purchase of medicinal products through the Internet (e-pharmacies), 3) the dispensation of medicinal products using drones and riders, and 4) the use of big data in the clinical trials of medicinal products. We are witnessing a new generation in medicinal products legislation: the generation of the digital society.

This digital society, which is able to break down walls that hinder the free dissemination of knowledge, presents a two-faced nature, like Janus, as it also leads, among other evils, to our personal data roaming freely looking for the highest bidder. The technological revolution has produced a new ecosystem (inhabited by social media, websites, blogs, etc.) and has put in check, almost on the verge of extinction, the personal data protection right[24] as well as other fundamental related rights (such as the right to honor or to one's own image). Moreover, the advance of digitalization is facilitating the appearance of new criminal behaviors, especially serious offences victimizing minors.[25]

21. OJ L311, 28.11.2001.
22. The transposition in Spain is dealt with by Royal Legislative Decree 1/2015 of 24 July, approving the consolidated text of the Law on Guarantees and Rational Use of Medicines and Medical Devices [*Real Decreto Legislativo 1/2015, de 24 de julio, por el que se aprueba el Texto Refundido de la Ley de garantías y uso racional de los medicamentos y productos sanitarios*] (TRLGURMPS). *BOE* [Spanish Official Gazette] 177, 25.07.2015. The current Spanish Law of Medicinal Products has been analyzed in detail in the collective work directed by Jordi Faus Santasusana and José Vida Fernández, *Tratado de Derecho Farmacéutico* (Thomson-Aranzadi 2017).
23. OJ L136, 30.04.2004.
24. Under our impassive eyes, even with naïve enthusiasm, we are witnessing the end of our privacy. Our privacy, our most personal sphere, circulates around the Internet with little or no control at all. The death of privacy is the object of the work of Ramón Orza Linares, 'El "derecho al olvido" contra la muerte de la privacidad' (2017) 12 REJP 5 et seq.
25. Some of them (like *sexting* and *stalking*) were not punished; the criminal code has therefore been modified in order to make these offenses punishable by law. We will

However, this digital society can also serve as support for the exercise of other fundamental rights, like freedom of speech and information or access to public information (transparency), that is, to guarantee democratic participation[26] as well as improve public services (especially in the health and medicinal product fields). This has recently become more apparent in the context of the COVID-19 crisis.[27] Ultimately, the digital society represents a challenge and an opportunity for the field of law.

There are many advantages that, at least in theory, we can derive from the effective implementation of the latest advances in the digital society in this sector (called e-health by some authors[28]), encompassed within concepts, such as accessibility, effectiveness, and efficiency. Think of the paradigmatic example of an elderly, chronic patient,[29] residing in an isolated rural area. This patient would not be required to go to a health center to be prescribed the medication required for his/her chronic illness,

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take as an example the work of Eloísa Pérez Conchillo in her book *Intimidad y difusión de sexting no consentido* (Tirant lo Blanch 2018); and the work of Aixa Gálvez Jiménez and Manuel Rodríguez Monserrat, 'Consecuencias jurídico-penales del juego online la ballena azul' in María del Carmen García Garnica and Nuria Marchal Escalona (dirs.), *Aproximación interdisciplinar a los retos actuales de protección de la infancia dentro y fuera de la familia* (Thomson-Aranzadi 2019).

26. The impact of the digital society on democratic participation has been addressed by Augusto Aguilar Calahorro, among other works, in 'Derecho de acceso a internet: libertad, democracia e igualdad' in Francisco Javier Durán Ruiz (dir.), *Desafíos de la protección de menores en la Sociedad digital. Internet, redes sociales y comunicación* (Tirant Lo Blanch 2018).

27. For an urgent critical remark on this respect, see the paper of Juan Luis Beltrán Aguirre, 'Información y transparencia en la gestión de la crisis sanitaria del COVID-19: balance crítico' (2020) 30(1) DS 81 et seq.

28. See Juan Francisco Pérez Gálvez (ed.), *Salud electrónica. Perspectiva y realidad* (Tirant lo Blanch 2017) or Juan Alejandro Martínez Navarro, *El Régimen Jurídico de la Salud Electrónica* (Tirant lo Blanch 2018).

29. Not only chronic patients but all of society can also benefit from the advantages that the rational use of technologies entail in the area of medicinal products. Let's think about Spain (and worldwide) during the COVID-19 crisis, where acting under the aphorism *salus publica suprema lex esto* the state of alert was decreed, which limited (to the point of suspension) fundamental rights and freedoms (especially freedom of movement). This subject is dealt with by Joaquín Sarrión Esteve in his work "Limitaciones a los derechos fundamentales en la declaración del estado de alarma para la gestión de la situación de crisis sanitaria ocasionada por el COVID-19," in the already mentioned book *Las respuestas del Derecho a las crisis de salud pública*. In this scenario, from the Mutuality of Civil Servants of the State (MUFACE) the implementation of the e-prescription system for these public employees, when they are users of the public health system, has been accelerated (before this, prescriptions for these public servants were only allowed in paper format) by reaching collaboration agreements with the different regional health services (like the Andalusian Health Service) in order to avoid unnecessary trips to the health centers to get those prescriptions.

and an e-pharmacy will be able to deliver it to his/her residence, through a drone. Is this a dream or a soon-to-be tangible reality?

However, the law cannot ignore the problems that this new scenario also brings, like self-medication or the acquisition of counterfeit medicinal products, digital illiteracy and the digital divide, the protection of patient data (Califano,[30] Donati,[31] or Laus[32]), the interoperability of computer systems, or the preservation conditions of medicinal products when transported using new technologies. The challenges and opportunities that arise here will be mainly addressed starting with the different instruments emanated in this respect from the institutions of the European Union (Bottari[33]) and analyzing their application in a member state, such as Spain.

In fact, the migratory phenomena (thanks to freedom of movement) or the spread of epidemics (like COVID-19) shows the requirement for building an interoperable European health system that protects patients' rights regarding cross-border healthcare (Álvarez González,[34] Cantero Martínez,[35] or Lorenzetti[36]).

II. ELECTRONIC MEDICAL PRESCRIPTIONS

The *medical prescription* is a mandatory and standardized health document by which physicians, odontologists, or podiatrists (the only health professionals entitled, within the scope of their specific competences, to prescribe medicinal products requiring a medical prescription in Spain, according to article 79 of the TRLGURMPS[37]) prescribe medicinal products or medical devices to patients, for their dispensation by pharmacists. The

30. Licia Califano, 'The Electronic Health Record (EHR): Legal Framework and Issues About Personal Data Protection' (2017) 19 (3–4) PPL 141 et seq. The author carefully examined the development of the electronic health record in the Italian legal system.
31. Daniele Donati, 'P.H.R. e Big Data. Some Juridical Considerations About the Digital Health Perspectives' (2017) 19(3–4) PPL 177 et seq.
32. Federico Laus, 'Digitization and Collection of Health Data in the EU Member States: A Comparative Perspective' (2017) 19(3–4) PPL 219 et seq.
33. Carlo Bottari, 'The European Regulatory Framework in eHealth Sector' (2017) 19(3–4) PPL 125 et seq.
34. Elsa M. Álvarez González (ed.), *Sanidad transfronteriza y libertad de circulación* (Tirant lo Blanch 2018).
35. Josefa Cantero Martínez (ed.), *La liberalización de la asistencia sanitaria transfronteriza en Europa. Retos y desafíos para el Sistema Nacional de Salud* (Thomson-Aranzadi 2017).
36. Diego Lorenzetti, 'Directive 2011/24/EU: The Application of Patients' Rights Regarding Cross-border Healthcare' (2017) 19(3–4) PPL 133 et seq.
37. In connection with the provisions of Spanish Law 44/2003, of 21 November, on the classification of healthcare professions [*Ley 44/2003, de 21 de noviembre, de ordenación de las profesiones sanitarias*]. *BOE* [Spanish Official Gazette] 280, 22.11.2003.

medical prescription is, therefore, one of the axes on which pharmaceutical care is articulated[38] in our health system. Obviously, the experience of Spain is not an isolated experience among its neighboring countries.[39]

Pharmacists dispense with a medical prescription those medicinal products that require it.[40] This requirement is to be specified on the package of the medicinal products. Medical prescriptions will be required for medicinal products that are likely to present a danger if used without medical supervision, even when used correctly; if they are frequently used in abnormal conditions and, as a result, are likely to pose a health risk; if they contain substances or preparations whose activity and adverse reactions require further investigation; or if they are normally prescribed by a physician to be administered parenterally (art. 19.2 TRLGURMPS).

It is essential to mention, but on another front, the *dispensation order*. In Spain, nurses[41] and physiotherapists might independently indicate, use, and authorize the dispensation of medicinal products and medical devices that are not subject to medical prescriptions related with their professional practice (art. 79.1 *in fine* TRLGURMPS). This dispensation order is the mandatory, standardized health document by which these professionals, within the scope of their competences and once they have been authorized individually through the corresponding certification, indicate or authorize, in the conditions and with the requirements provided for infirmary practice by Spanish Royal Decree 954/2015, of 23 October (modified by the Spanish Royal Decree 1302/2018, of 22 October)

38. For a deeper analysis of the legal system affecting pharmaceutical care, please refer, among others, to the following reference works: José Gustavo Quirós Hidalgo, *La prestación farmacéutica de la Seguridad Social* (Lex Nova 2006) or José Vida Fernández, 'La prestación farmacéutica' in José Luis Monereo Pérez *et al* (dirs.), *Comentario a la legislación reguladora de la sanidad en España. Régimen jurídico de la organización sanitaria, personal sanitario y prestaciones sanitarias* (Comares 2007).

39. As an example regarding electronic prescribing or electronic transfer of prescriptions in the UK, see Gordon E Appelbe and Joy Wingfield, *Dale and Appelbe's Pharmacy Law and Ethics* (9th edn, Pharmaceutical Press 2009).

40. In Spain, the competent authorities, within the framework of the provisions of European legislation and the TRLGURMPS, will classify medicinal products - with the effect that this has in the field of pharmaceutical care and the rational use of medicinal products - as follows: medicinal products subject to medical prescriptions or medicinal products not subject to medical prescriptions (art. 19.3 TRLGURMPS). The competent authorities may divide the first ones into medicinal products with renewable or not renewable medical prescriptions, medicinal products with special medical prescriptions, and medicinal products with restricted medical prescriptions, reserved for certain specialized means.

41. Nurse prescription is analyzed by Juan Francisco Pérez Gálvez (dir.), *Prescripción, indicación, uso y autorización de dispensación de medicamentos y productos sanitarios* (Tirant lo Blanch 2017).

for the dispensation of medicinal devices and products, subject or not to medical prescriptions, by pharmacists or under their supervision.

Without diminishing the guarantees provided in our legal system in this regard, new information and communication technologies have made the availability of e-prescriptions possible today. Its determined implementation by the Health Administration has displaced the traditional paper medical prescriptions. As the Andalusian Health Service has shown,[42] although its opinions might be extrapolated to other geographical areas of the country, the use of e-prescriptions present a series of advantages that are not only linked to saving the prescribing physician's or the long-term chronic patient's time (who does not have to go to his/her health center to get the prescriptions for continuing treatments that do not require further examination) but also enhancing pharmacovigilance, pharmaceutical services, and the fight against fraud, and increasing the physicians' time for their patients as well as facilitating smooth relations between the prescribing physician and the dispensing pharmacist, resulting in a very rational use of the medicinal product prescribed and allowing compliance surveillance.

The e-prescription also strengthens a new dimension acquired by the pharmacist in recent years, which is focusing on providing more personalized attention to the patient, known as *pharmaceutical service*.[43] In this context, the pharmacist must adapt to the different scenarios that may arise and try to ensure that the dispensation and subsequent pharmacovigilance[44] are both optimal in order to guarantee the patient proper access to the prescribed medicinal products. Hence, in Spain, article 79.5 of the TRLGURMPS provides that, in hospital dispensation orders and prescriptions, the physician shall include the relevant warnings for the pharmacist and the patient as well as the instructions for a better surveillance of the treatment.

This way, in Spain, the pharmaceutical dispensation regulation of the e-prescription allows the pharmacist to provisionally suspend the dispensing of a prescribed medicinal product when there are concerns about possible errors in the prescription, its appropriateness for the patient's condition, in cases of concomitant medication, or any other reason that may pose a risk to the health of the patient. This situation will

42. Document of frequently asked questions (FAQs) published by the Andalusian Health Service in: http://www.juntadeandalucia.es/servicioandaluzdesalud/principal/documentosacc.asp?pagina=gr_farmacia_2_1 (accessed on: 01.06.2020).
43. Carlos del Castillo Rodríguez, 'Políticas americanas de salud y de formación farmacéutica' (2011) 40(1) RCCQF 47 et seq.
44. Gabriel Doménech Pascual, *Régimen jurídico de la farmacovigilancia* (Thomson-Aranzadi 2009); and 'New European legislation on pharmacovigilance' (2011) 13(1,2) PPL 7 et seq.

be communicated to the patient and, electronically, to the professional who made the prescription and who will then be able to reactivate the prescription if required.[45] A separate field would be that regarding the possible conscientious objection of the pharmacist in charge of the dispensation of a medicinal product that poses a serious moral problem for this healthcare professional.[46]

Spanish Law 62/2003, of 30 December,[47] paved the way in this matter.[48] This regulation, in article 132.2, modifies article 85.6 of the old Spanish Law of Medicinal Products (1990) and establishes the implementation for the issuance/editing of e-prescriptions. Furthermore, this regulation provides that interested party consent will no longer be necessary for the treatment and transfer of data, which is according to the provisions of the Spanish Organic Law on Data Protection[49] (in line with the current General Data Protection Regulation).[50]

45. The Andalusian XXI prescription system allows the pharmacist to provisionally suspend the dispensing of a prescribed medicinal product when there are concerns about possible errors in the prescription, its appropriateness for the patient's condition, in cases of concomitant medication, or any other reason that may pose a risk to the health of the patient. This situation will be electronically communicated to the professional who made the prescription by filling in the report provided for the purpose in that system as well as to the patient. Within seven days after the provisional suspension, the prescribing professional can reactivate the relevant prescription if deemed appropriate (art. 11, sections first and second, DRME).
46. After Spanish Constitutional Court Judgment 145/2015, it seems that the mentioned court has recognized the possibility of an objection to the dispensation of an authorized and marketed medicinal product that was properly prescribed by a health professional certified to do that. In this ruling the Spanish Constitutional Court considers the appeal for legal protection requested — due to the violation of the right to conscientious objection, linked to the right of ideological freedom — by a Spanish pharmacist (from Seville) regarding the penalties imposed on the pharmacy that he ran due to a lack of stock of the active substance *levonorgestrel* (the so-called morning-after pill). This right to conscientious objection of the appellant would take precedence over the legal duty of the professional pharmacist of having a minimum stock available as established by the competent administrations (art. 86.3 of the TRLGURMPS).
47. Spanish Law 62/2003, of 30 December, on tax, administrative and social order measures [*Ley 62/2003, de 30 de diciembre, de medidas fiscales, administrativas y del orden social*]. *BOE* [Spanish Official Gazette] 313, 31.12.2003.
48. Although it is true that before this law, Spanish Law 16/2003, of 28 May, on the Cohesion and Quality of the National Health System (*BOE* [Spanish Official Gazette] 128, 29.05.2003), already foresaw for the first time in our legal system, in article 33, the possibility that these prescriptions could be extended or, where appropriate, edited in electronic form.
49. Spanish Organic Law 3/2018, of 5 December, on Personal Data Protection and Guarantee of Digital Rights [*Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales*]. Hereinafter referred to as LOPD. *BOE* [Spanish Official Gazette] 294, 07.12.2018.
50. Regulation (EU) 2016/679 (General Data Protection Regulation) in the current version of the OJ L119, 04.05.2016.

Along with the experiences of Project PISTA[51] at the national level, the truth is that, as always and[52] to the detriment of the already undermined Spanish National Health System (SNS), the regional administrations have been the most supportive on the implementation of e-prescription in Spain. We can especially underline the experiences of Galicia, Madrid, Valencia, and the region where we will focus our attention — Andalusia (*Receta XXI*).

The Andalusian Health Service, even though its opinions could be extrapolated to other geographical areas in and out of Spain, links the following advantages, among others, to the use of e-prescriptions: easier access for patients, especially those suffering from long-term chronic diseases, obviating the requirement for a health center visit to get medical prescriptions; increase the physicians' time for their patients by reducing the time spent filling in medical prescriptions to continue certain treatments that, according to their criteria, do not require further examination; allow the physician to check the dispensations made by the pharmacy for every prescription, allowing them to check adherence to treatments through compliance surveillance; facilitate smooth relations between the prescribing physician and the dispensing pharmacist regarding certain aspects of the treatment that might be important to the patient's health. They are an important tool for pharmacovigilance and the pharmaceutical service, and they substantially improve the fight against fraud (e.g., regarding doping in sports[53]) as the health card should be presented in every dispensation.[54]

In Andalusia, the e-prescription is regulated by Andalusian Decree 181/2007, of 19 June[55] (DRME), and it only affects the Andalusian Public Health System (SSPA). This regulation establishes the procedures and requirements for the prescription and dispensation of medicinal

51. Antonio Cordobés, 'Receta electrónica. Proyecto PISTA y repercusiones sobre la oficina de farmacia' (2002) 8-2 Offarm 142. This work tackles the advantages and inconveniences of Project PISTA (Promotion and Identification of Emerging Advanced Communication Systems), promoted by the Ministry of Science and Technology of the Spanish government.
52. Antonio Cordobés, 'Receta electrónica (II). Proyectos de las Comunidades Autónomas' (2002) 10-21 Offarm 148 et seq.
53. Francisco Miguel Bombillar Sáenz, 'El papel de la Agencia Española de Medicamentos y Productos Sanitarios en la lucha contra el dopaje en el deporte' in Ignacio Jiménez Soto and José Luis Pérez-Serrabona González (dirs.), *Los retos del deporte profesional y profesionalizado en la sociedad actual* (Reus 2017).
54. Please see the FAQs published by the Andalusian Health Service in: http://www.juntadeandalucia.es/servicioandaluzdesalud/principal/documentosacc.asp?pagina=gr_farmacia_2_1 (accessed on 01.06.2020).
55. *BOJA* (Andalusian Government Official Gazette) 123, 22.06.2007.

products and medical devices through e-prescription, understood as "the prescription issued on electronic format by a health professional qualified to do it," who shall prescribe medicinal products and medical devices, included in the pharmaceutical care of the SSPA (art. 2 DRME).[56]

In the Andalusian framework we also have to mention article 61 (Computerized Prescription) of Andalusian Law 22/2007, of 18 December, on the Pharmacy of Andalusia.[57] This indicates that, in order to facilitate access to pharmaceutical care for patients, in the jurisdiction of the SSPA, the prescription of medicinal products through the e-prescription computerized system will be promoted (although the official prescription pads could be preserved for cases and circumstances that the prescribing medical professional considers appropriate). The computerized systems supporting e-prescriptions must guarantee data confidentiality as well as allow traceability of the medicinal products.[58]

This regional regulation and experience cannot forget that the SSPA is part of the wider SNS. This is why the third additional disposition of the DRME, regarding the compatibility of computerized systems, establishes that it shall allow *compatibility* with management software programs for pharmacies and other medical prescription systems established in the SNS. According to article 78.3 of TRLGURMPS, the e-prescription shall be valid in the whole national territory (as the European Union Law defends its recognition in its 27 member states).

In this regard, this same provision of the TRLGURMPS, in its eighth section, points out that the government shall determine the minimum requirements that medical prescriptions issued or edited in electronic format must present in order to ensure that all citizens can access, in effective equality conditions, the pharmaceutical care of the SNS in the whole national territory. The interested party consent will no longer be necessary for the treatment and transfer of data, which is a consequence of the implementation of computerized systems based on

56. For a more in-depth analysis of this long-winded regulation, see my more extensive work 'Receta médica y venta de medicamentos online' in Juan Francisco Pérez Gálvez (ed.), *Salud electrónica. Perspectiva y realidad* (Tirant lo Blanch 2017). I understand that this work, which has a clear international profile, is more appropriate for an overall view, presenting the dynamics that guide the interventions of the Administration in this field, rather than describing, point by point, the control that, at a regulation level, this matter deserves nowadays in the Andalusian legal system.

57. *BOJA* 254, 28.12.2007.

58. The medicinal products catalog that should be included in the computerized prescription systems will be established by the competent body in the pharmaceutical care management of the SSPA, subject to a report of the Autonomous Commission for the Rational Use of Medicinal Products.

medical prescriptions either in paper or electronic format, according to the provisions of the LOPD. Those actions should have the purpose of facilitating the medical and pharmaceutical care of the patient and allow control of the SNS pharmaceutical care.

In this same line is Spanish Royal Decree 702/2013, of 20 September, amending Spanish Royal Decree 183/2004, of 30 January, on the regulation of the individual health card,[59] which identifies SNS users correctly and for life. This single individual health card format is a step toward the full implementation of the e-prescription and interoperable digital clinical history system. At present, 20 million Spanish citizens are already included in the digital clinical history database. Of them, 7.5 million digital clinical histories are shared with other European Union countries through the EPSOS project. Moreover, 61.5% of the issued and dispensed pharmaceutical prescriptions are already in the electronic format that comply with European requirements.

However, there is still a long way to go to attain the desired interoperability not only at a state level but also at the European level. In fact, the Andalusian Health Service warns its users that: "This system works in Andalusia, so if a user needs to acquire a medicinal product in another region, he/she should warn his/her physician in order to get the traditional medical prescription in paper format"[60].

The cross-border dimension also affects the prescription and dispensation of medicinal products.[61] Directive 2011/24/EU of the European Parliament and of the Council, of 9 March 2011, on the application of patients' rights in cross-border healthcare,[62] establishes the recognition of medical prescriptions issued in another member state. Article 11 imposes the recognition of medical prescriptions issued in another member state. If a medicinal product is authorized to be marketed on their territory,[63] in compliance with the European Union Law, the member states shall ensure that prescriptions[64] issued

59. *BOE* [Spanish Official Gazette] 238, 04.10.2013.

60. Please see the FAQs published by the Andalusian Health Service in: http://www.juntadeandalucia.es/servicioandaluzdesalud/principal/documentosacc.asp?pagina=gr_farmacia_2_1 (accessed on 01.06.2020).

61. I discuss this issue in depth in 'Cross-border Healthcare and Recognition of Medical Prescriptions Issued in Another Member State' (2017) 19(1–2) PPL 47 et seq.

62. OJ L88, 04.04.2011.

63. On a different matter, this recognition shall not affect any professional or ethical obligation (which includes conscientious objection) that could cause the pharmacist to not dispense the prescribed product (e.g., the dispensation of contraceptives).

64. Medicinal products shall be subject to medical prescriptions where they are likely to present a danger if used without medical supervision, even when used correctly;

in another member state for a named patient can be dispensed on their territory in compliance with their national legislation [article 11.2, section b)]. Two conditions must be present for this recognition to be possible: that medicinal products are authorized in both member states (origin state and treatment state) and that they have been prescribed by a professional legally entitled to do so.[65]

III. PURCHASE OF MEDICINAL PRODUCTS THROUGH THE INTERNET (E-PHARMACIES)

Over the last few years, a real digital common market has come into being.[66] European cross-border trade is being built on the trust (the e-confidence)[67] of consumers[68] in the context of electronic transactions. An example is the purchase of masks (some of them illegal) through platforms like *Amazon* during the COVID-19 crisis[69]or renting tourist accommodations through the *Airbnb* platform.[70] The use of electronic

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if they are frequently used in abnormal conditions and, as a result, are likely to pose a health risk; if they contain substances or preparations whose activity and adverse reactions require further investigation; or if they are normally prescribed by a doctor to be administered parenterally. See title VI, articles 70 et seq., of Directive 2001/83/EC.

65. The recognition of a medical prescription shall not affect the pharmacist's right — established, if applicable, in the national regulations of the treatment member state — to deny the dispensation of a medicinal product issued in another member state (affiliation member state) for ethical reasons, if the pharmacist is allowed to deny its dispensation if the medical prescription had been issued in the treatment member state.

66. See Paula Castaños Castro and José Antonio Castillo Parrilla (dirs.), *El Mercado Digital en la Unión Europea* (Reus 2018).

67. As highlighted in the Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee, and the Committee of the Regions, *Single Market Act Twelve Levers to Boost Growth and Strengthen Confidence "Working Together to Create New Growth"* (2011) COM 206 final, 13.04.2011.

68. To learn about the European citizen as a consumer, see Augusto Aguilar Calahorro, 'La Constitución de la Sociedad del Consumo: El Ciudadano Europeo como Ciudadano Consumidor' in Vasco Pereira Da Silva and Francisco Balaguer Callejón (coord.), *O constitucionalismo do séc. XXI na sua dimensão estadual, supranacional e global* (Instituto de Ciéncias Jurídico-Políticas 2015).

69. To this effect, the following website of the European Union and the national consumer authorities of the different member states reporting, with a vast deployment of documents, the illegal commercial practices detected in the context of the COVID-19 crisis, is interesting: https://ec.europa.eu/info/live-work-travel-eu/consumers/enforcement-consumer-protection/scams-related-covid-19_es (accessed on 01.06.2020).

70. The following works, among others, can be consulted about this collaborative economy platform: Ignacio Jiménez Soto, 'Ordenación de los servicios turísticos:

media fits well with mass contracting methods, where there are no great particularities that attend to the nature of the good or service contracted or the target consumer. Hence, it is conceived that it is possible to design automatic negotiation systems to solve all disputes that may arise through algorithms[71] and the appropriate software (without direct human intervention).[72]

The sale of medicinal products online, that is, through the Internet,[73] is regulated in the Spanish legal system by Spanish Royal Decree 870/2013, of 8 November[74] (RDVDM); it regulates the distance selling to the public of human use medicinal products not subject to medical prescriptions through websites (i.e., they do not require prescriptions). Through this statutory rule, the provisions established to this respect in Directive 2011/62/UE, of the European Parliament and of the Council, of 8 June 2011,[75] are incorporated in the Spanish law.

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competencias administrativas y unidad de mercado' in Tomás Font i Llovet and Luciano Vandelli (dirs.), *Ordenación jurídico-administrativa del turismo* (Atelier 2018) or Juan José Montero Pascual (dir.), *La regulación de la economía colaborativa Airbnb, BlaBlaCar, Uber y otras plataformas* (Tirant lo Blanch 2017).

71. We cannot go into detail here about the multiple problems that, from the point of view of law, we may have around the role of algorithms and artificial intelligence. Juan Francisco Sánchez Barrilao, among others, takes care of this matter in the following works: 'Los fundamentos del 'progreso informático' en la Unión Europea' (2017) 98 RDP-UNED 335 et seq or 'Derecho constitucional, desarrollo informático e inteligencia artificial: aproximación a la propuesta del Parlamento Europeo a favor de una regulación sobre robótica' in Javier Valls Prieto (coord.), *Retos jurídicos por la sociedad digital* (Thomson-Aranzadi 2018). A monographic study of this topic (algorithms) is developed in the book, directed by Alejandro Huergo Lora and coordinated by Gustavo Manuel Díaz González, *La regulación de los algoritmos* (Thomson-Aranzadi 2020).
72. The best doctrine has already revealed some of the legal problems that are posed by the online dispute resolution for consumers and, in particular, the adaptation of Spanish law to the European framework of alternative resolution (ADR) and online resolution (ODR). Let us think about, e.g., the work of Fernando Esteban de la Rosa (dir.) and Oriana Olariu (coord.), *La resolución de conflictos de consumo. La adaptación del derecho español al marco europeo de resolución alternativa (ADR) y en línea (ODR)* (Thomson-Aranzadi 2018).
73. Francisco Miguel Bombillar Sáenz, 'Receta médica y venta de medicamentos online' in Juan Francisco Pérez Gálvez (ed.), *Salud electrónica. Perspectiva y realidad* (Tirant lo Blanch 2017).
74. *Real Decreto 870/2013, de 8 de noviembre, por el que se regula la venta a distancia al público, a través de sitios web, de medicamentos de uso humano no sujetos a prescripción médica. BOE* [Spanish Official Gazette] 269, 09.11.2013.
75. Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products. OJ L174, 01.07.2011.

Spain, France (Leca[76] or Baes[77]), or Italy (Cini[78] or Minghetti[79]) form part of the group of countries that preserves medicinal products within the pharmacy circuit[80] (pharmacies or hospital pharmacies), which is a characteristic feature of the *Mediterranean* model of pharmacies, where this private establishment, although with public interest, is assigned with an important social role.[81] A good example of this is article 103 of the Spanish General Health Law,[82] which stipulates that "the custody, preservation and dispensation of medicinal products will correspond to legally established pharmacies." This model's purpose is to guarantee the quality and rational use of medicinal products, an optimum level of access by the population to pharmacies, and the excellence in training of pharmacists as health professionals.

Pharmacies will be established in areas where the regulations in force allow it, following some geographical (urban or rural area, distance with other already existing pharmacies, etc.) and demographical (regarding the quantification of the population that the pharmacy would be required to serve) criteria. In Spain, those regulations emanate from the corresponding Autonomous Communities, pursuant to the exclusive competence of the latter in terms of pharmaceutical planning,[83] through the relevant administrative procedure with authorizing nature aiming to guarantee the accessibility and quality of the service as well as sufficient supply of medicinal products.

Not only are we facing an oligopolistic reserve under which medicinal products can only be sold to the public in this type of establishments

76. Antoine Leca, *Droit Pharmaceutique* (Presses Universitaires d'Aix-Marseille 2006).
77. Celine Baes, 'La venta de medicamentos por Internet: un nuevo reto para los Estados miembros de la Unión Europea' in Rafael Barranco Vela (dir.) and Francisco Miguel Bombillar Sáenz (coord.), *El acceso al medicamento. Retos jurídicos actuales, intervención pública y su vinculación al derecho a la salud* (Comares 2010).
78. Maurizio Cini and Patrizia Rampinelli, *Principi di legislazione farmaceutica* (Edizioni Minerva Medica 2019).
79. Paola Minghetti, *La nuova normativa del farmaco – Il decreto legislativo 219/2006 confrontato con le direttive europee e la legislazione italiana precedente* (Tecniche Nouve 2007).
80. Francisca Villalba Pérez, *La profesión farmacéutica* (Marcial Pons 1997).
81. Juan Esteva de Sagrera and Pilar Martín Barea, *Función social de las oficinas de farmacia, Dispensación y cuidado de la salud* (Elsevier 2006).
82. *Ley 14/1986, 25th April, Spanish General Act for Health*. *BOE* [Spanish Official Gazette] 102, 29.04.1986.
83. Among other classic references, pharmaceutical planning has been studied by Miriam Cueto Pérez, *Ordenación farmacéutica: regulación estatal y autonómica* (Marcial Pons 1997); Antonio Ezquerra Huerva, 'El modelo español de ordenación farmacéutica en el contexto comunitario europeo de libertad de establecimiento' (2008) 32 RArAP 37 et seq; or Francisca Villalba Pérez, *La profesión farmacéutica* (Marcial Pons 1997).

but also, because of the particularities that these products present in connection to the health protection right, it can only be sold by individuals who are technically and professionally qualified to do so: pharmacists — a health profession that is subject to strong administrative interventions. This classical view has made countries like Spain traditionally reluctant to allow the sale of medicinal products through the Internet as this system was understood to not offer the minimum guarantees about the origin of the medicinal product, its efficacy, or its preservation conditions.[84]

Nevertheless, in the past few decades, especially after the ruling of the Court of Justice of the European Union (CJEU) in the *Doc Morris*[85] case, there has been some openness towards more liberalizing positions, especially when the so-called OTC[86] or promotional medicinal products

84. In Spain, Spanish Constitutional Court Judgment 152/2003, of 17 July, according to our Magna Carta, declared the Law of Pharmaceutical Planning of Galicia, contemplating the possibility of dispensing medicinal products subject to medical prescriptions to residences (through mail or courier service) to chronic patients, providing that the management of this process remained in the hands of a pharmacy, within the well-known pharmacy circuit. The Spanish Constitutional Court ruled that the sale was being arranged in the health establishment itself, and only the delivery was being deferred. According to our Constitutional Court: "[…] pharmacies can dispense, through mail or courier services, medicinal products that, for special circumstances, chronic patients need periodically, as long as their prescription is guaranteed by a medical prescription and there have been previous dispensations of the same medicinal product in that pharmacy […] and that […] the mail-order sale is not a door-to-door sale or indirect sale: the mail-order sale under appeal is arranged between the pharmacist and the patient in the establishment itself, with the peculiarity that the delivery of the medicinal product is made in deferred mode […]."

85. Case C-322/01 *Deutscher Apothekerverband eV v 0800 DocMorris NV and Jacques Waterval* [2003] ECRI-14887. The CJEU prosecutes, through this ruling, the sale on the Internet of medicinal products for human use, authorized in the Netherlands and Germany, some of which were to be dispensed under medical prescription by the *Doc Morris* pharmacy (the defendant). This pharmacy, which had an establishment open to the public in the Netherlands, delivered the medicinal products acquired, in person or through a courier service. In any case, the delivery was subject to the presentation of the corresponding medical prescription. This practice raised the suspicions of the *Deutscher Apothekerverband* (claimant), believing that it infringed the German law that prohibits the sale by mail-order of medicinal products whose dispensation is exclusively reserved to pharmacies located in its territory. The CJEU came to the conclusion that this prohibition is an equivalent effect measure that is not legally protected in article 30 of the Treaty. This provision could only be invoked to justify a prohibition affecting medicinal products that are subject to medical prescriptions.

86. This is the acronym for *over-the-counter*. We refer to medicinal products that are free, direct, or nonprescription sale. These are medicinal products produced, distributed, and sold to consumers/users to use on their own initiative. They are also called self-care products.

come into play, whose sale is not subject to medical prescriptions, on the understanding that their consumption does not imply any risks for the patient as long as the necessary measures to assure the guarantees provided in our legal system to ensure the protection of the consumer (especially the pharmaceutical service) are similarly adopted.[87] In the opinion of the CJEU, the situation changes when we talk about medicinal products that are subject to medical prescriptions, where the controls must be tightened in order to avoid abusive or incorrect use.[88] This position is the one established in the Community Directive of 2011. Consequently, only medicinal products that are not subject to medical prescription may be sold through distance selling.

The greatest danger that can arise from uncontrolled sale of medicinal products through the Internet is that the patient, contrary to all the rational use policies of medicinal products that prevail today, will fall into self-medication, avoiding the health professionals that should prescribe (physician) and dispense (pharmacist) the medicinal products according to our legal system, consuming medicinal products outside the pharmacy circuit and without the guarantees assigned to it (by the pharmaceutical service), putting his/her health and life at risk. The online sale of medicinal products should not infringe neither the provisions of our legal system that prevent direct advertising to the public of medicinal products that are subject to medical prescriptions[89] (art. 80.1 TRLGURMPS).

One of the biggest risks for public health that the sale of medicinal products outside the pharmacy circuit may entail, with the appearance

87. For the CJEU, section 106: "The only arguments which are capable of providing adequate reasons for prohibiting the mail-order trade in medicinal products are those relating to the need to provide individual advice to the client and to ensure his protection when he is supplied with medicines, and to the need to check that prescriptions are genuine, and to guarantee that medicinal products are widely available and sufficient to meet requirements."

88. In the words of the CJEU, section 119, this prohibition would be justified here: "Given that there may be risks attaching to the use of these medicinal products, the need to be able to check effectively and responsibly the authenticity of doctors' prescriptions and to ensure that the medicine is handed over either to the client himself, or to a person to whom its collection has been entrusted by the client, is such as to justify a prohibition on mail-order sales."

89. Regarding the advertising of medicinal products, see Nerea Iraculis, *La publicidad de los medicamentos* (La Ley 2009); Joaquín Cayón de las Cuevas, 'El tratamiento jurídico de la publicidad de medicamentos de uso humano: entre la libertad de empresa y la protección de la salud' in Josefa Cantero Martínez and Alberto Palomar Olmeda (dirs.), *Tratado de Derecho Sanitario* (vol. 2, Thomson-Aranzadi 2013); and, in particular, M. Asunción Torres López, 'La publicidad directa al público de los medicamentos con receta: el justo equilibrio entre los riesgos y beneficios' (2017) 109(1) RVAP 269 et seq.

of actors with spurious interests who use illegal techniques, is that their quality may not be assured, that the product marketed could not be a real medicinal product, and that the multiple controls — the already mentioned strong public health administrative interventions — established to protect the health of citizens could be circumvented. There are two scenarios that may serve to justify our concerns: counterfeit medicinal products and products with an intended health purpose (miracle products[90]).

In this sense, the Community Directive, transposed by the RDVDM, pays special attention to preventing the entry of counterfeit medicinal products into the supply chain. It is not known where they are manufactured (facilities), with what (raw materials used), or how (procedures). Substandard or counterfeit medicinal products are a real scourge, a serious public health problem. In the USA and in Europe,[91] approximately 1%[92] of medicinal products are counterfeit (most of them linked to doping products or sexual vigor). These substandard or low-quality medicinal products are illegal, illicitly manufactured, and without control measures regarding their ingredients or the manufacturing process. Counterfeit medicinal products, whose main way of access to the population is the Internet, are, in addition, outside the legal channel, without any guarantees regarding the distribution, storage, and preservation conditions required, which entails additional risks in case of consumption. As a consequence, public authorities must take extreme precautions and look for new and better tools to effectively tackle this problem in the context of the digital society. This is what is happening in the fight against doping.[93]

90. In line with Spanish Royal Decree 1907/1996, of 2 August, on the commercial promotion and advertising of products, activities, or services with an intended health purpose [*Real Decreto 1907/1996, de 2 de agosto, sobre publicidad y promoción comercial de productos, actividades o servicios con pretendida finalidad sanitaria*]. *BOE* [Spanish Official Gazette] 189, 06.08.1996.

91. WHO and European Union bodies have worked intensively against this problem in recent years, as shown, e.g., by Carlos del Castillo Rodríguez and Silvia Enríquez Fernández, 'Nuevo marco legal para la erradicación de los medicamentos falsificados: los nuevos dispositivos de seguridad' (2020) 61(1) Ars Pharm. 39 et seq.

    These efforts have led to Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use. OJ L348, 31.12.2010.

92. This problem especially affects developing countries. In Latin America and Africa, this figure rises to 30%. I refer to it in detail in 'Aspectos éticos y jurídicos de la investigación y comercialización de medicamentos para enfermedades olvidadas' in FARMAMUNDI (ed.), *Una reflexión sobre el comercio internacional, la propiedad intelectual y el derecho a la salud* (2015).

93. A disciplined fight in Spain for Organic Law 3/2013, of 20 June, on the protection of athlete's health and the fight against doping in sports [*Ley Orgánica 3/2013, de*

Regarding the benefits, *Doc Morris* itself reiterates them: "Internet buying may have certain advantages, such as the ability to place the order from home or the office, without the need to go out, and to have time to think about the questions to ask the pharmacists"; promoting, without neglecting the guarantees of the pharmaceutical service, agile, relevant, and interactive communication between the patient and the health professional.[94] In short, pharmacists still have all their functions, although the sale is made through the Internet, so they must ensure compliance with the guidelines established in the prescription by the physician who is responsible for the patient and cooperate with him/her in monitoring the treatment through the pharmaceutical service procedures (art. 86 TRLGURM), in favor of a rational use of the medicinal product.[95]

As for the conditions of the sale, we reiterate that only the pharmacies that are open to the public, legally authorized, and that are notified of this activity may carry out distance selling through websites of medicinal products that are not subject to medical prescriptions (art. 3.1 RDVDM). The

20 de junio, de protección de la salud del deportista y lucha contra el dopaje en la actividad deportiva. *BOE* [Spanish Official Gazette] 148, 21.06.2013. In this sense, the pharmacist in charge of the dispensation must also evaluate whether it is appropriate to dispense the medicinal product, especially when the amount requested exceeds the amount used in usual treatments, or in case of frequent or repeated requests indicating a possible misuse or abuse of the medicinal products that are being sold (art. 10.7 RDVDM).

94. Hence, for the order to be valid it must include the contact details of the buyer (name and surnames, telephone, email, and postal address) in order to allow the pharmacist responsible for the dispensation to contact him/her, send information regarding the treatment that allows its correct use, and to make the dispatch (art. 10.2 RDVDM). The pharmacist responsible for the dispensation may request from the medicinal product user, using the contact details provided by the latter, the additional information that he/she deems relevant in order to guide, advise, and instruct on its adequate use (art. 10.6 RDVDM). For a period of at least two years after the dispensation, pharmacies should keep a record of the orders supplied, with reference to the identification of the medicinal product, the quantity dispensed, the dispatch date, the details of the buyer, including the delivery address and the pharmacist responsible for the dispensation. That record shall be kept for the purposes of inspection and control by the competent authorities (art. 10.4 RDVDM).

95. This is something that the use of these websites might precisely consolidate. As stated by the CJEU itself in the *Doc Morris* case, section 114: "As to the argument that virtual pharmacists are less able to react than pharmacists in dispensaries, the disadvantages which have been mentioned in this regard concern, first, the fact that the medicine concerned may be incorrectly used and, second, the possibility that it may be abused. As regards incorrect use of the medicine, the risk thereof can be reduced through an increase in the number of on-line interactive features, which the client must use before being able to proceed to a purchase. As regards possible abuse, it is not apparent that for persons who wish to acquire non-prescription medicines unlawfully, purchase in a traditional pharmacy is more difficult than an internet purchase".

professional conduct of the pharmacist is an indispensable requirement for the dispensation of medicinal products to the public through websites (art. 10.5 RDVDM). Therefore, the sale must be concluded with the intervention of a pharmacist, from his/her pharmacy, and with previous personalized advice (art. 3.2 RDVDM). That is, the fact that the sale is made through the Internet should not imply the loss of guarantees for the protection of the health of the patients if there were not a pharmacy behind this transaction.

Therefore, the website must be considered as an extension of the activities of the pharmacy. Without going into all the details included in the statutory rules that govern the offer of medicinal products to the public through distance selling, I would like to emphasize on the importance of the websites (art. 8.3 RDVDM) to display a common logo, acting as a visa; to adapt to the provisions determined in the specific regulations of the European Union.[96] This website also will indicate the contact details of the competent health authority, the details of the administrative authorization system of the pharmacy, the name of its holder(s), the physical and electronic address of the pharmacy, the information about holidays or closed periods of the pharmacy, the estimated time for delivery of the medicinal products requested, the price of the medicinal products offered (indicating whether they include the applicable taxes), and the cost of the delivery service.

According to the provisions of articles 8 and 9 of the RDVDM, the website managed by the pharmacy may not offer or link to self-diagnostic or self-medication tools that omit the pharmacist's mandatory advice role in connection with the rational use policies of medicinal products. Medicinal products must be identified with the name of the authorized presentation and shall not include information that do not literally correspond with the current leaflets authorized by the Spanish Agency of Medicinal Products and Medical Devices (AEMPS). As far as the formal aspects are concerned, the information contained on the pharmacy's website must be clear, understandable, and easily accessible to the user (including those with special needs).

IV. DISPENSATION OF MEDICINAL PRODUCTS USING RIDERS

In short, the online sale of medicinal products has not undermined the traditional role assigned to pharmacies in our legal system. In this context,

96. Commission Implementing Regulation (EU) No 699/2014 of 24 June 2014 on the design of the common logo to identify persons offering medicinal products for sale at a distance from the public and the technical, electronic, and cryptographic requirements for verification of its authenticity. OJ L184, 25.06.2014.

we must understand the provisions of article 3.5 of the TRLGURMPS,[97] which prohibits the sale,[98] through mail and telematic procedures, of medicinal products and medical devices that are subject to medical prescriptions.[99] However, this same provision (as the RDVDM) allows the establishment by regulation of the applicable requirements and to regulate those sale arrangements regarding medicinal products that are not subject to medical prescriptions, assuring, in any case, that human use medicinal products are dispensed by or under the supervision of a pharmacist.

Two years ago, there was a dispute between the company *Glovo*[100] and AEMPS. The origin of their disagreement was that Glovo offered in its app the possibility for its riders to go to a pharmacy and buy medicinal products — not subject to medical prescriptions — and then take them to the client's residence, charging the client with a commission on the price of the medicinal products depending on factors, such as the distance between the pharmacy and the residence.

On July 1, 2018, the AEMPS issued a resolution compelling Glovo to stop[101] the door-to-door distribution of medicinal products not subject to prescriptions.[102] After that, Glovo has had no choice but to focus on the para-pharmacy market (e.g., intimate hygiene products or condoms).

97. The provisions of this section are without prejudice to the distribution or supply to entities legally authorized to dispense to the public.

98. It is therefore a very serious infringement: door-to-door sale of medicinal products, through the Internet or other telematic or indirect means, contrary to the provisions of that rule. Article 111.2.c).11 of the TRLGURMPS.

99. In any case, door-to-door sale and any kind of indirect sale of medicinal products to the public are prohibited. Health Administrations, on the grounds of public health or personal safety, may limit, prohibit, or put conditions on the door-to-door sale or any kind of indirect sale of health products to the public.

100. Rafael Sanz Gómez analyzes platforms like *Glovo*, *Deliveroo*, or *UberEats* by focusing on the transport of goods within the (controversial) phenomenon of collaborative transport, or rather, the collaborative economy. In these business models, *riders* (or *glovers*, in this case), operate as independent professionals, or self-employed, at least formally (something that has been discussed and denied by the courts in judgments like no. 244/2018, of 1 June, of the Social Court no. 6 of Valencia, regarding the platform *Deliveroo*). See 'The fast and the furious' nuevos modelos de negocio y cuestiones regulatorias y fiscales en el transporte colaborativo' in José Pedreira Menéndez (dir.), *Fiscalidad de la colaboración social* (Thomson-Aranzadi 2018).

101. This prohibition seems to have been repeatedly breached after that date: https://elpais.com/sociedad/2019/05/16/actualidad/1558006029_311844.html (accessed on 01/06/2020).

102. Glovo has waged a long conflict with the Federation of Pharmacies of Catalonia (Fefac), the Association of Pharmaceutical Companies of Madrid (Adefarma), the Andalusian employers' association Ceofa, and the General Council of Pharmaceutical Associations of Spain.

The AEMPS reported that, in 2018, it required the collaboration of buying and selling platforms, such as Amazon, *eBay*, *Milanuncios*, *AliExpress*, and *Wallapop,* in order to remove ads hosted on their platforms that promoted the illegal activity of selling medicinal products. By successfully collaborating, they removed a total of 139 ads.

The justification for this decision is very clear, as argued by the AEMPS: "Distance selling of medicinal products by telematic procedures can only be done through the websites of pharmacies that meet the requirements and conditions established in the mentioned Spanish Royal Decree 870/2013, of 8 November. No order or request for medicinal products by telematic procedures can be made to pharmacies if it is not directly through the website enabled for this purpose by the pharmacies".

The opposite would make impossible the guarantee of the safety of the medicinal product and open the door to fraudulent practices, such as the counterfeiting of medicinal products. Glovo claims that they do not sell or advertise medicinal products, that they merely connect users, pharmacies, and riders, who act as oral agents for the users that request the medicinal products.

This, however, is still an enormous incongruity when, in Spain, nursing homes purchase prescription drugs for their residents from the pharmacy that they deem convenient, often in another province, and transported in unregulated conditions, for several years now. In the Autonomous Community of Andalusia, this was the subject of Decree 512/2015, of 29 December, on the provision of pharmaceuticals in the residential social health centers of Andalusia.[103]

This idea connects with another regional experience in Spain: Galician Law 3/2019, of 2 July, on the recently approved pharmaceutical plan for Galicia.[104] Here, the delivery of medicinal products and medical devices to the patient's residence is addressed in an innovative way. Its article 7 establishes the special cases in which medicinal products and medical devices may be delivered to the residence. This delivery has an exceptional nature; it is not a new form of on-demand pharmaceutical service. Users cannot choose whether they want to come to the pharmacy in person or receive their medicinal products at residence.

103. *Decreto 512/2015, de 29 de diciembre, de prestación farmacéutica en los centros sociosanitarios residenciales de Andalucía*. *BOJA* 2, 05.01.2016. However, the Superior Court of Justice of Andalusia annulled in 2018 this Andalusian decree when considering that it invaded state competitions when legislating on pharmaceutical products and their conditions of prescription, dispensation, and supply.

104. *Ley 3/2019, de 2 de julio, de ordenación farmacéutica de Galicia*. *DOG* [Galician Official Gazette] 130, 10.07.2019.

In this line, it is considered that home delivery might be made to people who live in isolated rural areas and where there is a loss of functional autonomy and a requirement for assistance due to chronic diseases. In these cases, medicinal products and medical devices might be dispensed, with informed delivery, to their residence and always complying with the dispensing guarantees provided by the legislation. The delivery must be made by one of the five pharmacies that are closest to the patient's residence within the pharmaceutical area or, if expressly requested by the patient, by another pharmacy in the same reference area.

Hospital pharmacy services may also make home deliveries of medicinal products dispensed by hospitals, in accordance with the current state legislation. This possibility is also considered on an exceptional basis to promote the continuity of the assistance and avoid the patient from having to travel to the hospital.

In any case, the practical application of this new law will not be easy as it is subject to its regulatory implementation. Its text includes express references to future regulations that should define the essential elements for such practical application. In this regard, it is considered that a future decree will regulate the control methods or systems that must be followed to ensure compliance with the guarantees regarding the quality and health control of the deliveries, the cases where home delivery of medicinal products dispensed by hospitals are justified as well as the procedure for hospital pharmacy services to make these deliveries. In the same way, it will be necessary to define what is meant by "informed delivery."

V. DISPENSATION OF MEDICINAL PRODUCTS USING DRONES

Drones are one of the most promising technological devices for civilian (and military) applications today (Sarrión Esteve[105]). In this sense, as an example, the applications of remote-controlled piloted civilian aircrafts for scientific documentation are well known,[106] in particular, for geological, architectural, archaeological, or engineering works. These remotely

105. Joaquín Sarrión Esteve, 'El régimen jurídico de la utilización de los drones. Una aproximación multinivel a la legislación europea y española' (2017) 12 REJP 103 et seq.

106. Aerial photographs and recordings as well as aerial photogrammetry, 3D maps, 3D point clouds, digital terrain and surface models, rectified orthomosaics, volume calculations, contour lines, 3D models with textures, etc. In fact, the University of Granada has had a drone unit for some years now within the Image Processing Service of the Scientific Instrumentation Center (CIC), and designed to carry out all work requiring the flight of unmanned vehicles and authorized as an official operator registered with the Spanish Air Safety Agency.

piloted aircrafts, which are very useful in capturing aerial images, also play an important role in the field of photography and journalism (which has been called *dronalism*).[107] Not to mention the use of these devices by the Public Administration itself in the exercise of its powers (such as imposing a sanction or managing emergencies[108]).

Different studies have addressed the legal problems that these drones may pose while flying through European skies (de Miguel Molina and Santamarina-Campos,[109] Fox,[110] or Lavallée[111]). In Spain, the rules currently governing these devices can be found in Regulation (EC) no. 2018/1139, on common rules in the field of civil aviation and establishing a European Aviation Safety Agency[112]; in article 50 and following Spanish Law 18/2014, of 15 October, approving urgent measures for its growth, competitiveness, and efficiency[113]; and especially in Spanish Royal Decree 1036/2017, of 15 December, regulating the civilian use of remotely piloted aircrafts[114] and modifying Spanish Royal Decree 552/2014, of 27 June, developing the Rules of the Air and common operative dispositions for services and aerial navigation procedures and Spanish Royal Decree 57/2002, of 18 January, approving the Air Traffic Regulation. However, beyond these rules of general nature, these devices also have to respect

107. This is why these devices require adequate regulation to guarantee the protection of fundamental rights that may be in conflict here (including, of course, data protection) since it is clear to everyone that their activities can often involve virtual interference, violating article 18.2 of the Spanish Constitution [as already considered in Supreme Court Judgment (Criminal Court, Section 1) no. 329/2016 of 20 April].
108. Which was recently highlighted in Spanish Decree 70/2017, of 2 June, of the Valencian Council, modifying the Territorial Emergency Plan of the Valencian Community, because of the approval of the procedure for the operation of remotely piloted aircraft in emergency situations under the direction of the Generalitat.
109. María de Miguel Molina and Virginia Santamarina-Campos, *Ethics and Civil Drones. European Policies and Proposals for the Industry* (Springer International Publishing 2018).
110. Sara Fox, 'Positioning the Drone: Policing the "Risky" Skies. Issues' (2019) 18(2) ALP 295 et seq.
111. Chantal Lavallée, 'The Single European Sky: A Window of Opportunity for EU–NATO Relations' (2017) 26(3) European Security 415 et seq.
112. OJ L212, 22.8.2018.
113. *Ley 18/2014, de 15 de octubre, de aprobación de medidas urgentes para el crecimiento, la competitividad y la eficiencia. BOE* [Spanish Official Gazette] 252, 17.10.2014.
114. *Real Decreto 1036/2017, de 15 de diciembre, por el que se regula la utilización civil de las aeronaves pilotadas por control remoto, y se modifican el Real Decreto 552/2014, de 27 de junio, por el que se desarrolla el Reglamento del aire y disposiciones operativas comunes para los servicios y procedimientos de navegación aérea y el Real Decreto 57/2002, de 18 de enero, por el que se aprueba el Reglamento de Circulación Aérea. BOE* [Spanish Official Gazette] 316, 29.12.2017.

a series of prohibitions regarding civilian use that can be found all over our legal system.[115]

As far as drones — a field of application still to be explored — are concerned, in May 2019 we learned that the pharmaceutical distribution cooperative Novaltia was participating in the *Pharmadron* project in order to analyze the viability of distributing medicinal products to inaccessible (mainly rural) areas using drones.[116] This way, chronic patients, elderly people, and those who live in areas that are difficult to access by land transport (because of their orography, adverse weather conditions, or some kind of disaster suffered) could utilize this device.

Nevertheless, it is not only necessary to ensure the autonomy and capacity of the drone to travel to its destination but also that it complies with the guarantees required by the Good Distribution Practices. For this reason, a specific container, which is refrigerated (between 15°C and 25°C), aerodynamic, and light (25 kilos, of which 10 will be payload), is being tested. In any case, current legislation does not allow the distribution of goods with commercial drones[117] (something that we know Amazon has been demanding in other places).

If the distance selling and dispensation of medicinal products through drones were to be allowed, according to our barely exposed Mediterranean

115. Let's think about the regulations, both at state and regional levels, that interact when regulating the use of drones in an environment such as the National Park of Sierra Nevada in order to ensure the conservation of the park, preserving its flora and fauna, which could be endangered by the activity of these motorized aircraft. Technological innovations have led to these devices, drones, which can be very useful in the mountains in emergency situations (e.g., to locate a person lost in an avalanche) but also could alter the balance of this particular ecosystem. The law cannot ignore their existence, and therefore will have to set relevant limits to their use. I discuss this in 'Práctica de actividades deportivas en Espacios Naturales Protegidos y uso de drones con ocasión de las mismas: el caso del Parque Nacional de Sierra Nevada' in Manuel Titos Martínez *et al* (eds.), *Actas del I Congreso Internacional de las Montañas Sierra Nevada 2018* (Editorial Universidad de Granada, 2019).

116. It is something that is already being successfully tested in other places. In Rwanda, a drone traveling at 100 kilometers per hour carries bags of blood, vaccines, and medicinal products to remote areas of the country (such as those in the border with the Democratic Republic of Congo and around lake Kivu). A four-hour journey by land, due to its abrupt geography and poor land communications, can be done in fifteen minutes. The medicinal products or the blood are transported in carefully packed packages of one and a half kilograms, which are parachuted over hospitals and health centers, informed beforehand by text message. This experience that shortens distances and brings welfare closer is narrated by Ramón Casilda Béjar in pages 364 and 365 of the book *Capitalismo, crisis y reinvención* (Tirant Humanidades 2019).

117. Joaquín Sarrión Esteve, 'Introducción a la regulación del uso civil de los drones' (2018) 207 CEFLegal 91 et seq.

pharmacy model, this operation could only be done through the websites of the pharmacies that meet the requirements and conditions established in the RDVDM, that is, within the pharmacy circuit, under the guidance and direction of pharmaceutical professionals, guaranteeing pharmaceutical service, pharmacovigilance, and traceability. To sum up, the fact that the delivery is made through a drone should not imply the loss of guarantees for the protection of the health of the patients if there were not a pharmacy behind this operation.

For this purpose, we could also apply the provisions of the RDVDM regarding the transport and delivery of medicinal products to the user. It indicates that the supply of medicinal products from the dispensing pharmacy to the address indicated by the user will be the sole responsibility of the pharmacy. The transport and delivery of the medicinal product must be done in such a way as to ensure that it does not suffer any alteration or decrease in quality (art. 11.1 RDVDM). In case the transport of the medicinal products is carried out by a third party (the logical thing to do if a drone is required to be operated), there should exist a contract establishing the responsibilities of each party, the conditions of the service, and the provisions of the LOPD. In that case, the responsible pharmacist should inform the contracted carrier about the required conditions of transport and should ensure that these conditions are maintained during transport (e.g., avoid breaking the cold chain), especially in the case of thermolabile medicinal products[118] (art. 11.2 RDVDM).

The provisions of the RDVDM regarding returns would also be applicable. The pharmacy cannot accept returns of medicinal products once they have been dispensed and delivered to the client by the drone, except in the case of medicinal products that have been supplied by mistake, if they do not correspond to the ones ordered, or if they have been damaged during transport. In all cases, the returned medicinal products will be destroyed through the existing waste management integrated systems[119] (art. 12.1 RDVDM). The user consumer would be entitled to return the medicinal product and the refund of the amount paid in the event that the delivery time exceeds 50% of the time established in the purchase for reasons not attributable to it (art. 12.2 RDVDM).

118. Insulins, vaccines, certain eye drops, and some antibiotics. Also, medicinal products that should be kept in refrigerators between 2°C and 8°C. It is very important not to break the cold chain from manufacturing to administration (to the patient).

119. SIGRE Medicamento y Medio Ambiente, a nonprofit entity created to guarantee the correct environmental management of packaging and medicinal products residues of domestic origin, plays an important role here.

Sometimes it seems that these drones are part of a dystopian story more typical of a novel of the cyberpunk genre. But I think it is necessary to contemplate all its potentialities, without overlooking its edges, without underestimating the problems that may arise from its use. In short, it is the legislator's mission to mark the appropriate limits to the use of this technology. For this reason, I wanted to end this section by venturing, as a *lege ferenda* proposal, what the regulation of the dispensing of medicinal products through drones could be in the near future. These motorized devices, accompanied by the appropriate regulation, I am convinced, can be a very useful instrument in bringing distances closer together and, with this, contribute to social welfare.

VI. USE OF BIG DATA IN CLINICAL TRIALS WITH MEDICINAL PRODUCTS

A clinical trial is understood as,[120] according to Regulation (EU) no 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC[121]: "any investigation in relation to humans intended: (a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products; (b) to identify any adverse reactions to one or more medicinal products; or (c) to study the absorption, distribution, metabolism and excretion of one or more medicinal products; with the objective of ascertaining the safety and/or efficacy of those medicinal products"[122].

There is a normative acquis that regulates, among other aspects, the rights and guarantees of subjects participating in a trial as well as the functions and obligations of the different persons involved in a trial: sponsor, monitor, and investigator. The subject exposed to the trial must provide his/her informed consent to participate in it, being aware of the objectives of the trial, its risks, the conditions under which it will be

120. Fernando Antúnez Estévez, 'Los ensayos clínicos' in Pilar Rivas Vallejo and María Dolores García Valverde (eds.), *Derecho y Medicina. Cuestiones jurídicas para profesionales de la salud* (Thomson-Aranzadi 2009).

121. OJ L158, 27.5.2014.

122. Clinical trials are classified in different phases (I, II, III, and IV), depending on the number and characteristics of subjects participating in them. In addition, depending on the technique used to perform them, we can talk about "random" or "randomized" and "masked" or "blind" trials; and, according to the number of centers participating, we can distinguish, in the same way, between "single-center" or "multi-center" trials; and lastly, depending on their methodology, between "controlled" or "non-controlled" trials.

carried out, and his/her right to withdraw at any time from it. In this sense, and according to our legal system, clinical trials would be designed, carried out, and communicated with full respect for the rights, safety, and welfare of the trial subjects, as ensured by the ethics committees and health authorities of the different states.[123]

It is not possible for a researcher to hide behind consents full of lawless and indeterminate terms in order to carry out any research. All the regulatory instruments, at supranational [the Charter of Fundamental Rights[124] or the Oviedo Convention[125] and its additional Protocols on the Prohibition of Cloning Human Beings, on Transplantation of Organs and Tissues of Human Origin (2002) and on Biomedical Research (2004)] and national levels (Spanish Law of Biomedical Research[126]) as well as others of ethical nature (the Helsinki Declaration[127]), concern biomedical research without losing sight of its close connection and implications with the ensemble of all fundamental rights. The advance of science and knowledge and health innovation should not warrant, in any case, a decrease in the exercise of fundamental rights.[128]

123. In Spain, besides the TRLGURMPS, we must pay attention to Spanish Royal Decree 1090/2015, of 4 December, regulating clinical trials with medicinal products, the Ethics Committees of Research with Medicinal Products, and the Spanish Registry of Clinical Studies [*Real Decreto 1090/2015, de 4 de diciembre, por el que se regulan los ensayos clínicos con medicamentos, los Comités de Ética de la Investigación con medicamentos y el Registro Español de Estudios Clínicos*]. *BOE* [Spanish Official Gazette] 307, 24/12/2015. In Spain, AEMPS is in charge of authorizing, modifying, suspending, or revoking clinical trials of medicinal products and medical devices as well as authorizing the import of medicinal products not authorized in Spain for their use in clinical trials, while the specialized organs of the Autonomous Communities shall ensure that the ethical principles that should govern this type of research are respected.
124. OJ L326, 26.10.2012.
125. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine), made in Oviedo on April 4, 1997.
126. Spanish Law 14/2007, of 3 July, of biomedical research [*Ley 14/2007, de 3 de julio, de ordenación farmacéutica de Galicia*]. *BOE* [Spanish Official Gazette] 159, 04.07.2007.
127. From the World Medical Association. The last modification took place in the 64th General Assembly, in Fortaleza, in 2013.
128. For example, I defended these ideas in the area of biomedical research and biobanks in 'Legal Approach for Informed Consent and Donation of Biological Samples to Biobanks for Biomedical Research: A Glance to Spain' in Rainer Arnold, Roberto Cippitani, and Valentina Colcelli (eds.), *Genetic Information and Individual Rights* (Regensburg Universität 2018).

    Informed consent must also be guaranteed in scenarios such as that of COVID-19. This is indicated by the Spanish Medicines Agency in its document "Medidas excepcionales aplicables a los ensayos clínicos para gestionar los problemas derivados de la emergencia por COVID-19," 05.05.2020.

Ethical committees[129] are independent bodies constituted by health professionals and nonmedical members (including legal practitioners), responsible for ensuring the protection of the rights, safety, and welfare of subjects participating in a trial, and for providing public guarantee thereof by means of an opinion, prior to the commencement of the corresponding clinical trial,[130] which analyzes the relevance of the trial and its design, the evaluation of foreseeable risks and benefits, its protocol, the suitability of the investigators and the adequacy of the facilities, methods, and documents to be used to inform the trial subjects in order to obtain their informed consent, insurance or compensations covering the liability of the investigator and sponsor, or the subjects' recruiting arrangements, including the agreed upon economic and contractual terms.

Incidentally, the work of these committees also benefits from the use of new technologies by allowing the regulation of the administrative procedures to which they conform, to conduct their meetings[131] by teleconference, videoconferences, or any other similar system, provided that the identity of the members or persons replacing them, the content of their declarations (authenticity), the time at which these occur, the interactivity and intercommunication between them in real time (unit of event), and the availability of the media during the session, are guaranteed. Consequently, these committees could constitute, convene, and conduct their sessions, adopt agreements, and send minutes both in person and remotely.

129. In Andalusia, one of the committees is the Coordinating Committee on the Ethics of Biomedical Research in Andalusia (CCEIBA), who, in cooperation with the local Ethics Committees of Research, establishes the proper mechanisms for the coordination of methodological, ethical, and legal evaluation of clinical trials and post-authorization studies with medicinal products for human use, within the framework of the provisions of Spanish Decree 8/2020, of 30 January, regulating the ethical care and biomedical research bodies in Andalusia. *BOJA* [Andalusian Official Gazette] G24, 05/02/2020.

130. Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC entered into force on June 16, 2014. On the role of these ethical committees in this new legislative scenario, see Íñigo De Miguel Beriain *et al*, 'An EU Comparative Analysis of the Regulation of Clinical Trials Supervisory Bodies in the Aftermath of Regulation 536/2014' (2020) 26(2) EPL 307 et seq. I also dealt with this in the paper 'Breves notas en torno al nuevo Reglamento UE de ensayos clínicos' (2014) 217 ADS 569 et seq.

131. As stated in article 17.1 of Spanish Law 40/2015, of 1 October, on the Legal Regime of the Public Sector [*Ley 40/2015, de 1 de octubre, de Régimen Jurídico del Sector Público*] (*BOE* [Spanish Official Gazette] 236, 02.10.2015) as well as in article 16.6 of the mentioned Spanish Royal Decree 1090/2015. In this regard, see the work of Jesús Conde Antequera, 'La Administración electrónica. Cuestiones jurídicas básicas' in Estanislao Arana García (dir.), *Conceptos para el estudio del Derecho Administrativo I en el Grado* (6th edn, Tecnos 2019).

One of the aspects that these ethics committees must control is the use of big data techniques. There exist many doubts, not only in legal terms, regarding the reliability of these techniques. These data mining processes are not well defined yet, providing results that do not respond to any pattern in many cases. That is, the products resulting from the use of these techniques are merely simple data accumulation without any kind of order to systematize them. In other words, given the actual state of these techniques, human intervention is essential if we want to avoid getting simple aggregated data sets. I've been able to verify this firsthand after analyzing many of these projects as a chairperson in ethics committees of biomedical research and from my conversations with computer experts specializing in the field.

In addition, another concern is the lack of literacy in the use of new technologies, as much as we identify ourselves as digital natives. Citizens do not know or understand what big data is. In 2014, Europol participated in the experiment in which a group of investigators installed a free Wi-Fi point in London.[132] Under the terms and conditions, people were requested to sign a "Herod Clause" that promised free wifi only if the recipient accepted to surrender his/her first child for eternity to the company providing the connection. Sixty-six people registered.

Beyond my initial reservations about it, I cannot deny the potential of big data for improving health services and eHealth or digital health[133] as long as these red lines are not crossed: the right to privacy or the right to personal data protection, along with nondiscrimination of certain persons or groups by automated decision-making processes based on profiles (even more when, as I previously mentioned, these techniques are not completely reliable).

The collection and analyses of massive amounts of information continuously and in real time have changed the way forecasts and decisions are made. All possible data are collected and then those that will serve the intended purpose are extracted. In the health field, whether

132. This example was brought up by Joaquín Cayón de las Cuevas from his lecture "La dimensión jurídica de la inteligencia artificial en salud: asignaturas pendientes y desafíos futuros," in the context of the Conference *GRX HEALTH DATA. Inteligencia Artificial y Salud: Destino Común*, held in the Andalusian School of Public Health on November 14, 2019.

133. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions "Towards a Thriving Data-driven Economy." COM/2014/0442 final/. There it is stated: "This global trend holds enormous potential in various fields, ranging from health, food security, climate and resource efficiency to energy, intelligent transport systems and smart cities, which Europe cannot afford to miss".

in the care area or, in particular, in that of biomedical research, this new scenario opens the door to vast future prospects, reducing health costs and improving service, which will be more personalized, leading to more predictive, preventive, and participative medicine.

These are its lights, but we must be careful with its shadows. As happens with any innovation, the key is in this technology's use, which makes obsolete the techniques that until now we have tried to protect our privacy and our personal data with.

In any case, we must act with great caution in this field and avoid making false steps. For instance, under the LOPD empire, public administrators have done much to request consent to use the data of more than eight million people that are users of the Andalusian Health Service, explaining the specific uses that the Health Administration was going to make of them. Thus, in the big data era, are we going to allow computer experts from a certain company access, all in one go, to all records and conduct on them all the data processing operations that they deem convenient?

According to Durán Ruiz,[134] we must advocate to change the focus of responsibility from the data subject to the controller, that in practice are the users of the data (organizations, companies, administrations, etc.); that is, to move towards a system that is accountable for the responsible custody of data and not merely for compliance with the rules established for the provision of consent so that the time to adopt precautions would be the time when the data are used instead of when they are collected (to which the current model of informed consent responds).[135]

VII. FINAL THOUGHTS BY WAY OF CONCLUSION

Through this contribution, we have checked that the recent regulatory changes (at European, state, and regional levels), with the intention of bringing the tools of the digital society to the field of prescription and dispensation of medicinal products, do not represent any break with the

134. Francisco Javier Durán Ruiz, 'Big data aplicado a la mejora de los servicios públicos y protección de datos personales' (2017) 12 REJP 33 et seq.

135. The self-regulation and adherence to the codes of conduct of the designers of these programs might be a first way out, while developing new, generalized, and international rules establishing common standards of privacy and data protection. This way, the need to protect privacy from the very moment the technology is designed must be considered (e.g., that in a social media platform the default privacy options are the most protective ones). Nevertheless, and given the high economic value of our data, this is the same as *having the wolf looking after the sheep.*

Mediterranean pharmacy model that prevails in Spain. We are bringing its logic up to date.

The prescription still remains in the hands of the physician and the dispensation in those of the pharmacist. The electronic medical prescription and the online sale of medicinal products do not imply any impairment of the functions previously assigned by our legal system to pharmacists or attack to the role of pharmacies as private health establishments with public interest. The prescription and dispensation of medicinal products is still moving, as, within the pharmacy circuit, the best understood medium, guarantying the protection of the health of the population, ensuring the quality and rational use of medicinal products, and vanquishing the serious risks of self-medication or abuse.

The advantages, at least from the theoretical view, are numerous: the possibility of calmly placing orders from a residence or not having a chronic patient going to the health center to renew a prescription (which also saves time for the physician). Yet, the most important aspect is that both the purchase of medicinal products on the Internet and electronic medical prescriptions enhance the guarantees specific to the pharmaceutical service and ensure the correct therapeutic information, better follow-up of pharmacological treatments, and a coherent and articulated network system of pharmacovigilance; in short, they enable an interactive exchange, agile and relevant, between the patient and the health professionals in charge of the prescription and the dispensation of these medicinal products.

Thus, according to the famous quotation by the character of Tancredo from the novel *The Leopard*: "If we want things to stay as they are, things will have to change."[136] Advances in the digital society have not altered the essence of the work of pharmacists, it has only modulated it.

In the context of drones, the Law — and, in particular, Administrative Law — cannot turn its back on these unmanned aerial vehicles, on this disruptive technology; these motorized devices have come to stay, and ignoring its existence is not an option. Drones are not the *anacronópete* of Enrique Gaspar y Rimbau; they are a more than tangible reality that cannot be orphaned by regulation. Hence, these drones are controlled, in a more or less direct or indirect way, by the complex regulatory framework that is our legal system.

136. The Italian original of this quotation is "*Se vogliamo che tutto rimanga com'è bisogna che tutto cambi*." *The Leopard* (*Il Gattopardo*) is a novel by Giuseppe Tomasi di Lampedusa that chronicles masterfully the changes in Sicilian life and society during the *Risorgimento*. It was published in 1958 and made into a film of the same name in 1963 by Luchino Visconti.

However, it is obvious that the regulations we have today do not yet provide all the necessary keys to confront with solvency the challenges that this technology puts on the table of the legislator, who has to weigh, with a high view, the pros and cons associated with the civilian use of these drones. As in other fields linked to technological innovation or biomedical research, there is neither the necessity to blindly embrace this technology (like the *balm of Fierabrás*) nor to demonize it.

Technological tools of the digital society offer us endless possibilities in order to protect our health. They provide us with better weapons for this fight in which human beings are aware of their vulnerability. The COVID-19 crisis has shown, e.g., that good geolocation computer applications (along with other measures), well implemented technically and respectful of our fundamental rights, would have undoubtedly facilitated the work of the trackers and, therefore, helped prevent the spread of infections among the population.

However, we reiterate, contrary to Machiavelli's opinion, the end does not justify the means. To embrace this technical advance should not imply breaking with our Mediterranean pharmacy model or with the guarantees offered by the fact that the medicinal products move within the official circuit. Before and now, the professional who knows the most about it, the pharmacist, has to look after this particular health good. Moreover, we cannot fall into an immobility that prevents progress. Risk is inherent in our current society. Zero risk does not exist (the drugs themselves are not totally safe). To safeguard our health public is required a risk/benefit balance managed within the framework of our Rule of Law, without jeopardizing the rights that protect us and that have cost us so much to achieve. This story will be a dystopia if we as a society (and especially jurists) allow it to be.

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