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Rare Diseases in Spain and Argentina - We Share the Same Reality

Alvaro Lavandeira Hermoso[1]*, Maria Carolina Regis[2], Alvaro Lavandeira Dalama[3] and Alberto De La Montana[3]

[1]Lawyer, Juris Doctor by the San Pablo-CEU University, Spain-M De La O ts, who does not lose faith? but also hope.

Law is becoming increasingly dynamic as it must respond to people's new needs which in an increasingly glo balised world means considering international solutions. In recent years new technologies the collapse of health systems the progress of science and genetics the pharmaceutical industry quality clinical trials and the contri bution of knowledge from the Associations of patients with Rare or Uncommon Diseases have generated new factual assumptions that are the o ject of study de bate proposal and solution. is is how the law of people matters how to continue riding.

In this opportunity a brief analysis of the legislative and conceptual evolution of the notion of Rare or Uncommon Diseases is presented. It then considers the national regulations in Argentina and Spain and therefore in the European Union and international regulations governing R.D. or R. .F.D. which indicate the need to adapt the laws to social needs and a bve all to the time required to implement them and guarantee the quality of life of patients. And nally it details the di erent resources and solutions both pu lic and private that comparative law has given to R.D. or R. .F.D.

illions of people in the world su er from low prevalence diseases most of which have no treatment: these are the so called "rare diseases" "infrequent diseases" or even "orphan diseases" .

e latter term refers to the limited interest among basic and clinical researchers in the study of the pathogenesis diagnosis and treatment of these diseases as it is very difficult to nd pu lic or private sources of funding.

Rare minority or infrequent diseases group together a heterogeneous set of life threatening or chronically de bilitating diseases a ecting according to EU regulations a maximum of 5 out of every 10 000 inha bitants in Europe. It is estimated that there are between 5 000 and 8 000 di erent rare diseases a ecting 6 8% of the world's population. In case the disease a ects less than 1 in 50 000 people we are talking a bout an ultra rare disease.

It is estimated that in Spain the num ber of people su ering from a rare disease is more than 3 million people.

In Argentina a rare disease (R D) is considered to b those pathologies whose prevalence in the population is equal to or less than 1 person per 2 000 inha bitants as esta lished b National Act No. 26 68 on omprehensive Health are for eople with Rare Diseases and their Families.

Eighty per cent of rare or minority diseases are of genetic origin and a ect both children and adults. In general they are progressive de bilitating and degenerative and often cause chronic pain and consequent deterioration in quality of life for su erers. In fact 65% of these pathologies are serious disa bling and highly complex and in half of the cases they produce motor sensory or intellectual de cits that lead to a disa bility in the autonomy of the su erer. Furthermore the mor b mortality rate is very high so much so that in 50% of cases

***Corresponding author:** Alvaro Lavandeira Hermoso, Lawyer, Juris Doctor by the San Pablo-CEU University, Spain, E-mail: alvaro.lavandeira@yahoo.es

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or low prevalence diseases represent a real challenge in terms of public health due to the various factors that make their diagnosis and treatment difficult.

On the one hand the lack of sufficient information and experts makes obtaining a diagnosis an excessively long and complicated process as it often takes years from the appearance of the first symptoms to the definitive diagnosis of the disease.

The average time it takes for a person affected by a rare disease to obtain a diagnosis is almost 5 years and in some cases it can even take up to 10 years.

The lack of scientific knowledge and specialised professionals and therefore of effective treatments for most rare diseases means that the quality of health care for these patients is not the most adequate.

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human being to maintain functional organic normality both physical and mental and to be restored when a disturbance occurs within the degree of development reached by medical science in order to recover the quality of life while prolonging its life cycle if treated according to the provisions of the treating physicians

In Argentina Act No. 26.68 was passed in 2011 which aims to promote comprehensive health care for people with rare diseases. This law promotes the right to access and health care for patients with this type of pathology regulates the creation of an organisation specialised in rare diseases and establishes the obligation to draw up a list of rare diseases in accordance with the prevalence of pathologies in the country.

The regulatory articles extend to other responsibilities among which it is specified that clinical care for these people must be covered by social security and prepaid medicine companies.

This norm was regulated only four (4) years later by Decree of the National Executive Power N° 74/2015 dated 11 May 2015. In its second article it specifies such diseases as those whose prevalence in the population is equal to or less than 1 in 2000 people according to the national epidemiological situation.

The goals to be achieved by the Authority of Application are given within the framework of the National Programme for Rare Diseases created by Decree 74/15 regulating the E oF act (art. 3°) and which is within the orbit of the Undersecretariat of Medicines and Strategic Information dependent on the Secretariat of Access to Health (Res. 18 2/20 of the National Ministry of Health) of which the Honorary Advisory Council is a member. Its purpose is to promote comprehensive access to health care for people living with an E oF with the elaboration of the List of Rare Diseases (which in February 2021 was officially approved by Res. 641/51 of the Ministry of Health) and the National Registry of Patients with E F which is part of the Argentine Integrated Health Information System both objectives are set by Act No. 26.68 .

In Spain competences in health management are transferred to the Autonomous Communities although the bases and general coordination of health care as well as legislation on pharmaceutical products depend on the central government. This means that the care of R.D. which requires a high degree of specialisation is an important area of coordination within the health competences between the Autonomous Communities.

In the world R.D. began to occupy a place on the public agenda as such at the end of the 1 0s. And Spain began to take steps to address RD in 2000 starting with research in parallel to the first regulatory efforts at European level. It should be recalled that Spain joined the European Economic Community now the European Union by signing the accession treaty in 1 85 which came into force on 1 January 1 86.

The role of the European Union in the field of health is to promote cooperation between Member States and where necessary to support their action. The objective has always been to establish a comprehensive Community strategy to support Member States in providing effective and efficient recognition prevention diagnosis treatment care and research for rare diseases in Europe.

Depending on the Member State or region in which they live EU citizens have unequal access to specialised services and available treatments. A few Member States have successfully addressed some of the issues raised by the rarity of these diseases while others have not yet explored possible solutions.

Under the responsibility of the Commission and the EMA (European Medicines Agency) a policy is already being implemented in the field of orphan drugs for example.

Prior to the Orphan Medicinal Products Regulation therefore the European Community understood that the problem of rare diseases required a special concerted effort to avoid significant morbidity or mortality or a significant reduction in the quality of life or socio economic potential of the people suffering from them. The Community authorities believed that the Community could provide added value to Member States' actions on rare diseases.

Prior to the adoption of the regulation only eight drugs for rare diseases had been authorised. As of today there are around 200 medicines available for almost a hundred different pathologies along with more than 2 000 orphan designations.

On 24 March 2021 the European Union published Regulation (EU) 2021/522 of the European Parliament and(t) 5(i) .1(t a) s (c) (n U)43(nio)(
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