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RIGHT TO HEALTH CARE OF THE PEOPLE SUFFERING FROM RARE DISEASES – CASE STUDY OF SERBIA LEGISLATION

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ABSTRACT

People with rare diseases are facing with numerous challenges in exercising right to health care. Access to health care system is often limited taking into account that there is still lacking the classification and codification of the rarest diseases. The revision version of the International Classification of Diseases of the World Health Organization (ICD-11) is scheduled to be realized in 2018 and is expected to include the category of rare diseases as well. Serbia amended Health Care Law establishing the centers for rare diseases and adopted the new Prevention and diagnosis of genetic diseases, genetic conditioned anomaly and rare diseases Law (2015). This paper aims to provide analysis of the medico-legal status of patients with rare diseases in Serbia considering the European Union legislation and recent trends in international policy and law in this field.

Key words: right to health care, rare diseases, codification and classification system, access to health care, Serbia legislation.

INTRODUCTION

Research studies in the field of rare diseases are still ongoing in their basic scientific areas such as medicine and biology. This could be a significant challenge for legal researchers to address the legal implications in this matter. People with rare diseases are presented as vulnerable and marginalized social group whose socio-economic rights could be violated, regarding that they affect a very small percentage of the population and that there is still no single universally accepted definition of rare diseases. Consequently, the classification and codification of most rare diseases are lacking, which makes people with rare diseases invisible in health care system. Issues regarding patient-physician relationship in terms of health care and specially genetic privacy and informed consent have been subject of most recent articles in this area (Mascalzoni, et al., 2014; Budych et al., 2012; Grady et al., 2012, Gainotti et al., 2016; Giannuzzi et al., 2017;). The access of the patients to treatment and drugs for rare diseases (so-called orphan drugs) is limited; therefore the participation in clinical trials is often required. It implies that informed consent is important legal issue to be considered in a process of providing health care. Furthermore, concept of the public health care insurance covering rare diseases diagnostic and treatment procedures is significant for rare diseases patients, especially in developing countries such as Serbia, taking into account the high cost of orphan drugs. In this respect, there is a number of research papers deal with orphan drug regulation in terms of drug development, reimbursement policies and fair drug access (Davies, 2012; Gammie et al., 2015; Mincarone, 2017). This paper aims to analyze medico-legal status of patients with rare diseases in Serbia, primary their access to diagnoses and treatment, taking into account health care and health insurance regulation as well as the regulation that specially address rare diseases issues adopted in 2015. Serbia has received a status of candidate country in a process of accession to the European Union, so the European Union regulation in the field of rare diseases will be considered.

DEFINITION, CODIFICATION AND CLASSIFICATION OF RARE DISEASES – CURRENT CHALLENGES

In so far, there is no universally accepted definition for rare diseases. It differs between legislation and policy although the prevailing view is that statistical criteria regarding the prevalence, less often incidence of the disease, is crucial in defining rare diseases (Richter 2015, 913-914). The problem arises from a small number of person affected (in each country and worldwide), heterogeneity in origin, diversity of symptoms manifestation, and variation in prevalence and frequency of diseases

among states. All this leads to problems in codification[112] and classification of rare diseases. A lack of appropriate definition, codification and classification of rare diseases in medical terms create uncertainly for people affected in achieving social roles and exercising their fundamental human rights. So, some states where patients' organization are strong enacted legislation that is primary dealing with orphan drugs containing the definition of rare diseases as well (Aymé, Bellet and Rath 2015, 2). The United States of America was the first country that defined rare diseases in the Orphan Drug Act (1983) - "a disease is considered rare when it affects less than one per 1,250 individuals in terms of prevalence" (Kodra 2012, 1026-1028). In European Union, rare diseases are those that affect no more than one in 2000 individuals (Schieppati, et al 2008, 2039) or no more than five in 10,000 people in the European Union (Regulation (EC) No 141/2000 of orphan medicinal products). On the other side, China has the largest population affected but the difficulties in defining rare diseases still remain, and there is no universally accepted definition across the country. In policy documents the definition of the World Health Organization (WHO) - rare diseases are defined as diseases with an incidence of 0.65-1% - is the most commonly used although the definitions of the United States of America and European Union have been used as reference as well (Cui and Han 2017, 148). From patients' human rights perspective the most important issue is to include definition of rare diseases in national policy and legal documents regardless of the fact whether it will be adopted from the WHO, EU or USA documents. The definition needs to be unique and valid across the county.

Defining rare diseases in policy terms is a step forward to dealing with codification and classification issues where all together influence on social and legal status of individuals with rare diseases. Modern diseases classifications (presuppose the codification of the disease) are based on different classification principles, namely, on an etiological principle (infection diseases, external causes), on a patho-physiological (endocrine disorders) or on an anatomical principle (cardiovascular diseases, respiratory diseases) (Mackenbach 2004, 225). The classification principle in a field of rare diseases should be based on a multiple classification criterion, considering the heterogeneity and diversity of rare diseases. The most applicable is the Orphanet classification system of rare diseases. The Orphanet classification system was established under the supervision and with financial support of the European Commission where information about rare diseases was collected and classified in a manner where each clinical entity has been assigned a unique Orpha number (Aymé, Bellet and Rath 2015, 2). This classification was mainly based on scientific grounds where clinical and etiological principle dominated followed by

[112] Codification means that diseases have an individual, unique code, so that they could be easily recognized within a health information system.

poly-hierarchy approach in the context of rare diseases that affecting several body systems (*Ibidem*). The Orphanet classification model will serve as a base for revising the WHO International Classification of diseases (version 10) whose 11 version needs to include all relevant rare diseases and is scheduled to be realized in 2018.

New WHO codification and classification model will be used in health care information systems providing the identification of rare diseases patients and ensuring entitlement of the right to diagnosis and adequate treatment. It would significantly improve the status of rare diseases patients in health care system, make the patients visible and recognized as a special health category with particular needs that are to be considered from health care policy as well as wider social policy aspect. Patients with rare diseases represent a vulnerable category of health care users whose "vulnerability" could be addressed as a "positive marking" in order to exercise their right to health care (Stojković Zlatanović 2015, 387). Recognition of the vulnerable health status for rare diseases patients in the health information system (special coding according the WHO classification system in rare diseases registries) is necessary in order to ensure their visibility. Moreover, it could be a part of the state positive discrimination policy setting out special measures for health care protection of vulnerable patients. In modern law the concept of specialization of needs of different social and health groups is stressed accompanied by specialized measures that need to be incorporated in domestic legislation (Stojković Zlatanović 2016, 97). The measures of positive discrimination policy supposed to be temporary lasting by the time needed to ensure equity but the specificity of the status of rare diseases patients ("rarity" of the diseases) requires permanent policy and legal answer to address the problem of their invisibility.

EUROPEAN UNION REGULATION IN THE FIELD OF RARE DISEASES

The European Union (EU) engagement in the field of rare diseases was of crucial significance for development of policy and legal framework in the Member States in this matter. The first document that addressed this issue, containing current definition of the diseases, was the Regulation EC 141/2000 of Orphan Medicinal Products. This document was created to set out standards in the field of rare diseases and improve patients care especially access to effective treatment (Rodwell, Aymé 2015, 2329). The main problem of the patients is delayed diagnosis often misdiagnoses, creating delayed therapies sometimes the absence of specific therapies in national health care system that have a great influence to life quality and life span of individuals. Also, the problem of poor medical expertise among health professionals, limited public awareness about rare diseases and a small number of marked approved orphan drugs is noticed (Aagaard, Kristensen 2014, 39). On this grounds, the EU continue to

develop a policy guidelines and adopted in 2009 the Recommendation on an Action in the Field of Rare diseases aiming to address specific needs of rare diseases patients (Dharss et al. 2017, 2). The Recommendation is a soft law document, legally no-binding, that support adoption of rare diseases strategies/plans on national level as a part of public health care policy and law. Along this, arising of public awareness and visibility of rare diseases, research development, the empowerment of patients organizations, and creation of centers of expertise for rare diseases are key elements of the Recommendation and central for national strategies/plans (Rodwell, Aymé 2015, 2331). The EU, also, addressed, explicitly, rare diseases in the Directive 2011/24/EU on patents rights in cross-border health care in Article 13. The Directive was issued on March, 2011 and was to be implemented in Member States national law by October, 2013 (Aagaard, Kristensen 2014, 40). The Article 13 deals with issues regarding EU support mechanisms that would help health professionals in a process of diagnose and treatment of rare diseases, particularly how to use Orphanet database and European reference network[113] (Directive 2011/24/EU on patents rights in cross-border health care). The second part of the Article 13 deals with the subject of cross-border health care in terms of rare diseases, i.e. member states need to set measures in order to make patients, health professionals and health care bodies aware about possibilities offered by the Regulation 883/2004/EC regarding national funding of diagnoses and treatment which are not available in the Member State affiliation (*Ibidem*). The Article 20 of the Regulation 883/2004/EC is important for the medico-legal status of patients with rare diseases, taking into account the availability of specific treatment in national health care system. It means that, if appropriate treatment could not be received in Member State of residence, the insured person could seek care in another Member State with adequate health care resources. But there is a condition regarding authorization by the competent institutions of Member State of residence which will be accorded if the treatment in question is among the benefits provided by the legislation in that Member State and that treatment cannot be given in appropriate time period which is medically justifiable, taking into account patients current state of health and probably course of the disease.

In most member states, patients organization have crucial role in establishment and adoption of national strategies/plans influencing national legal framework in this field. However, the analyses showed substantial differences in rare diseases infrastructure among States where most countries (France, Germany, the UK, Bulgaria) have developed or announced intentions to develop national rare diseases strategies/plans (Dharss et al. 2017, 12). All of them, except France, did not finish the implementation process (*Ibidem*). The economic power of the state plays the

[113] European reference network is virtual network involving health care providers across Europe created in order to facilitate cooperation between national centers of expertise.

important role in development of rare diseases programs with an influence on the national health care spending.

SERBIAN LAW AND POLICY – IMPROVING MEDICO-LEGAL STATUS OF PATIENTS WITH RARE DISEASES

The Article 92a of the Serbia Health Care Law addresses the issue of rare diseases in terms of creation of centers of expertise (centers for rare diseases) as a part of current health care institutions that need to be established on tertiary level of health care. Under the jurisdiction of the centers of expertise are - diagnostic procedures for patients with rare diseases, prenatal and neonatal screening, genetic counseling, care of patients with rare diseases, keeping records of patients with rare diseases for the territory of the Republic of Serbia (rare diseases registries), cooperation with foreign reference centers for the diagnosis and treatment of rare diseases, as well as with a network of European and world organizations for rare diseases, and continuous education in the field of rare diseases (Health Care Law, 2017, 92a). Draft Health Care Law (2017) was not changed in the part that deals with rare diseases. Health care Insurance Law does not contain specific standards regarding the costs of diagnostics and treatment of rare diseases that will be covered by public insurance.
However, Serbia adopted Regulation on conditions of cross-border health care. According to this document, treatment outside domestic health care system could be approved to insured patient where all cost of the treatment in question will be reimbursed if disease could not be successfully treated in Serbia. This provision has been applied to all diseases including those that are recognized as "rare". The list of rare diseases could be found on the web site of the Ministry of Health but it is not clear how (what criteria has been used) and who (what institution) did the list. However, for the treatment of rare diseases it is necessary to provide proof of low incidence of the disease according to statistical data that need to be gathered from health care institution who suggested cross-border treatment. Also, there is one more condition – the treatment conducted abroad must be completely successful i.e. should lead to full hilling healing of the patient. This provision is questionable given that most rare diseases are serious, chronic condition, life-threatening with frequent phases of remission often leading to long-term disabilities, so it could not be expected to claim with great possibility a completely hilling a complete healing of the patient. It limited the patients' suffering from rare diseases in exercising their right to health care and seriously endangered the principle of equity in health. Furthermore, in the Regulation, rare diseases have been explicitly mentioned in terms of diagnosis procedures. It means that diagnosis could be determined abroad only for "rare" not for other so-called "common" diseases. Under the diagnosis of rare diseases, it is understood the sending of samples of biological material for analysis abroad and the

condition is the same as for treatment – diagnosis could not be provided in the Republic of Serbia. It is important to notice that this document beside the criteria of law incidence, define rare diseases as genetic in origin excluding protection for the patients whose genetic status could not be bond for particular rare disease. Having said that, privacy in terms of diagnostic procedure is important issue to consider, particularly when sensitive genetic information had to be collected (Stojković Zlatanović, Sovilj 2017, 188). Serbia adopted the Prevention and diagnosis of genetic diseases, genetically conditioned anomaly and rare diseases Law in 2015. The intention of the legislator was to give narrow explanation of the diagnostic issue in the field of rare diseases aimed at dealing with the problem of delay in diagnosis and misdiagnosis in this matter. But if we analyze the article 29-30 dealing with rare diseases diagnosis, it could be inferred that provisions are almost the same as those in the Regulation on conditions of cross-border health care. In Article 31 the period for determination of the diagnosis in domestic health care system is limited to six months. If, after that period, health condition of the patient deteriorates, special Multidisciplinary Health care Commission[114] will give the recommendation for conducting additional diagnostic procedures abroad. The final decision will be made by the Republic Health Care Insurance Fund.

At the time of adoption, the Prevention and diagnosis of genetic diseases, genetically conditioned anomaly and rare diseases Law was announced as law that will particularly address the issue of rare diseases resolving the main problems of patients in their access to health care. This Law only repeated the provisions from the Regulation on cross-border health care addressing only rare diseases that are genetic in origin. Meanwhile Serbia joined the active reforms in health care sector, and amended basic health care legislation (Health Care Law, Health Insurance Law); it also adopted modern Biomedical Assisted Fertilization Law in 2017 (Sovilj, Stojković Zlatanović 2017, 286). New additional standards addressing the issue of health care for patients with rare diseases are not contained in these documents. The characteristics of data about rare diseases patients that need to be collected by health care institutions are not addressed in the Draft of Health Care Law. It is not clarified the issue of whether registers will be maintained by the rare diseases patients or by rare diseases. Patient registries need to be organized databases that contain information including demographic, medical, and family history that is being collected, stored, and available for retrieval via standardized and secure methods (Lochmüller et al. 2017, 1298).

CONCLUSION

[114] According the data presented in a Bulletin of one of the patients' organization for rare diseases the Multidisciplinary Health Care Commission has not met more than 3 years.

Serbia regulated centers for rare diseases and set out conditions for diagnosis and treatment outside of national health care system by legally binding documents although there is still no comprehensive policy framework represented in the form of strategy document as recommended by the EU action policy in a field of public health. The adoption of the National strategy for rare diseases was announced in 2014 but until now the document was not presented to the public. So, a number of questions regarding medico-legal status of patients with rare diseases still remain open. Nationally accepted definition of rare diseases, the question of standardized registries, privacy issues concerning data sharing and protection of the databases in centers of rare diseases are noticed as challenges that need to be addressed in the policy documents. Additionally, current provisions presented in the Prevention and diagnosis of genetic diseases, genetically conditioned anomaly and rare diseases Law and Regulation on cross-border health care about treatment and diagnosis of rare diseases outside the national health care system could limit patients with rare diseases in exercising their right to health care. In Serbia, the provisions regarding treatment and diagnosis outside the national health care system are set out on the same basis as those in the EU, both requiring the authorization by the competent national authority. The problem arises from the provision requesting the "completely healing" of the patient who received health care abroad. The empowerment of patients' organizations that was set out by the EU regulation is another issue that needs to be considered in a Serbian policy approach in this field. Patients' organization are leading force when it comes to understanding the needs and specificity of medico-legal status of individuals living with rare diseases, especially in terms of so-called "ultra-rare" diseases. Their role in establishment of public policy and law could not be neglected and public authorities must cooperate in a process of setting out and implementing the adopted standards. Moreover, the experts from medicine science, biology as well as social sciences (sociology, psychology and law) must participate in adoption of the national strategy for rare disease.

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