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Labour Rights of the Rare Diseases Population – Breaking the Glass Ceiling

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ABSTRACT

This paper aims to introduce a legal framework for exercising one of the most basic socio-economic rights of people with rare diseases: the right to decent work. Considering the specificity of the medical and, consequently, social status of the people affected, the appropriate labour-law measures need to be determined. Applying the comparative and normative method along with the contemporary anti-discrimination principle, the labour status of the rare diseases population has been analysed based on the proposed classification in legal terms. As a precondition for labour legislation, new Serbian healthcare legislation on rare diseases should be supported through the process of implementation to reduce adverse cases as effectively as possible, advance genetic and other clinical diagnoses, and thus increase the efficiency of available medical treatment. Concerning public health policy, updated registries and better health statistics should be created. These activities require certain amendments to both general and specialist labour legislation (disability legislation), aiming to include patients with rare diseases in the working (and social) environment without discrimination.

KEY WORDS

rare diseases population | labour status | anti-discrimination law | legal classification | dignity

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INTRODUCTION

Nowadays, patients with rare diseases form a social group with particular needs whose fulfilment implies the achievement of fundamental human rights. In their efforts to improve their socio-legal status and exercise these rights, patients and their family members have established associations that seem to have eventually crossed national borders and acquired the character of regional organisations that aim to improve people's right to healthcare and other related social rights.[1] Consequently, people with rare diseases are identified as representing a vulnerable social group with all the characteristics of health minorities (Lerner 2003: 8).

Minority social groups are those whose needs do not match the needs of the majority population. Acknowledging this is significant in allowing these groups to exercise a fundamental human right (Satterfield, Mertz and Slovic 2004: 1115): the right to a dignified life.[2] In the past, the differentiation of minority groups from the majority population was based mostly on religious, ethical, and linguistic differences, but later differentiation has also been made based on people's health status in the context of increased health risks (Pasqualucci 2008: 31). Vulnerability as a sociological characteristic of minority groups is a feature of all social groups, regardless of their ethical, religious, or other status if there are significant inequalities in exercising their fundamental human rights. Vulnerable social groups and vulnerable populations are considered to be mostly "religious minority groups, the economically disadvantaged, the very sick, or institutionalised people". Additionally, the concept of vulnerability as an ethical and sociological principle is closely related to the legal principles of justice and the concept of the prohibition of discrimination (Levine et al. 2004: 45). In contemporary legal systems, any form of differentiation, exclusion, or limitation based on various grounds aimed at or leading to the denial or limitation of fundamental human rights and the fulfilment of elementary needs represents discrimination sanctioned by legal norms.

The health status of patients with rare diseases and the activities of their daily and working life are closely linked. Most rare diseases (80%) are of genetic origin, which necessitates legal protection against cases of genet-

[1] By "social rights" we consider also the broader term 'socio-economic rights' *i.e.* the right to education, right to work, right to healthcare, right to social protection and care etc. without going into further determination of any possible differences between social and socio-economic rights (Tushnet 1992: 25). About this issue, also see: Young (2008: 113).

[2] By "right to dignified life" we considered „not only the right of every human being not to be deprived of his life arbitrarily, but also the right that he will not be prevented from having access to the conditions that guarantee a dignified life (*Vida Digna*)" that stands in favour of the interdisciplinary approach of this article *i.e.* taking into consideration the healthcare and labour status of people with rare diseases as prerequisites for dignified life (Pasqualucci 2008: 31).

ic discrimination. On the other hand, a person's working capacity is determined by his/her medical status and the requirements of the particular job. Thus, several developed countries have adopted anti-discrimination laws regarding genetic privacy in health insurance and labour (Erwin 2008: 869).

According to the Statute of the World Health Organization, the concept of human health is defined as a person's complete state of physical, mental, and social wellbeing, so the complexity of the legal status and difficulties in protecting patients' rights have to be considered (Üstün and Jakob 2005: 802). The third component of health suggests the inclusion of patients with rare diseases in the social environment, which consequently means inclusion in the working environment, free from any form of discrimination. At the regional level, the European Union's recommendations referring to healthcare in the field of rare diseases require a global approach based on special and combined efforts to improve the quality of life and socio-economic potential of affected people (Council Recommendation on an action in the field of rare diseases 2009; Directive of the European Parliament and of the Council on the application of patients' rights in cross-border health care 2011). Aside from this, they emphasise the need to empower patients with rare diseases as a pre-condition for health, encouraging proactive measures to improve quality of life amongst the chronically ill (Council Recommendation on an action in the field of rare diseases 2009).

In the literature, the prevailing opinion is that the concept of 'quality of life' is multifaceted and covers the following five aspects: physical, material, social, and emotional wellbeing, as well as development and activity (Felce and Perry 1995: 60). Along with this narrative, the physical aspect of people's health, mobility, and physical safety is closely linked to the material side of health, including income/finance, security, food/meals, and worldly possessions (Felce and Perry 1995: 61). So, the research hypothesis relies on the interconnection of the notions – the quality of life and general wellbeing of patients with rare diseases as a 'prerequisite for health,' implying the necessity for broader regulation, *i.e.* the regulation of both the medico-legal and labour status of those people. A holistic and integrative approach would also favour mutual regulation in healthcare and labour regarding the status of people with rare diseases. Furthermore, according to European Union recommendations, Member states should encourage centres of expertise to be based on a multidisciplinary approach addressing the needs of people with rare diseases. That suggests the inclusion of broader, passive social policy and active employment measures to improve living conditions for patients affected by rare diseases and their families.

THE CONCEPT AND CLASSIFICATION OF RARE DISEASES

Today, there is neither a unique classification, nor even a generally accepted definition of rare diseases. Defining rare diseases on an international level, establishing a registry of rare diseases, and defining health and other problems that patients with rare diseases face are all of great importance for affected people's general status. Such a registry would require the adequate classification and codification of rare diseases, as well as the policy possibility of establishing rare diseases registries, registries of the people affected, or both. These are lacking in Serbia (although some preconditions for their creation have been established). At the European level, the most important such registry is the Orphanet classification of rare diseases based on a clinical principle where approximately 5,400 rare diseases have been listed in the Orphanet database, while the classification and codification of rare diseases for the latest version of the International Classification of Diseases (ICD-11) – which was released by the World Health Organization (2018) – uses the Orphanet system as a template for updating international terminologies (Rath et al. 2012: 804). The main reason for the invisibility of rare diseases in both international and national healthcare coding systems is the individual rarity of genetic and other types of rare diseases, which leads to uncertainty in exercising fundamental human rights for affected people (Aymé, Bellet and Rath 2015).

Statistical data on the incidence of the manifestation of certain diseases in particular geographic areas (Besag and Newell 1991: 1) are used for defining rare diseases. The criteria for rarity are defined by national regulatory bodies. The definitions of rare diseases are different in various states depending on the development of registries and available medical services regarding healthcare planning and allocation of scarce resources. In 2009, the European Union adopted the Recommendations in the Field of Rare Diseases, which are not legally binding for Member states, and instead represent an instrument of so-called 'soft law.' Nevertheless, they create a political and moral obligation for Member states to make a framework for the regulation of rare diseases in national healthcare systems.

European soft-law instruments have great significance nowadays, particularly in terms of regulating issues under the exclusive jurisdiction of Member states. This refers to social policy issues including both healthcare and employment policies (Trubek and Trubek 2005: 351). In the field of social security, based on the Treaty Establishing the European Community, the method of coordination has been applied to adjust social security systems amongst Member states, stressing that, in this area, existing EU legislation on social security does not aim to replace each state's national systems, but instead strives to guarantee that the right of free movement laid down in the Treaty of the Foundation of the European Union can be fully exercised (De la Rosa 2005:

620). On the other hand, for specific domains, the dominant method in the European Union is the method of harmonisation, which implies the change of the national legislation by which the differences in the legislation of Member states have to be eliminated (De la Rosa 2005: 249). The method of harmonisation is applied by adopting directives and rules, whereas the method of coordination is applied by adopting recommendations, guidelines, strategies, and action plans.

The EU Recommendation on Action in the Field of Rare Diseases (2009) defines rare diseases based on their prevalence *i.e.* all diseases that affect fewer than five in 10,000 people in the European Union are classified as rare. This definition is taken from the Action Plan in the Field of Rare Diseases, implemented between 1999 and 2003. The same definition is used in the European Council and Parliament Regulation on Orphan Medicinal Products (1999). Earlier, in 1983, the concept of rare diseases was presented in the legislation of the United States of America *i.e.* in the Orphan Drug Act (1983), where rare diseases were considered to be those affecting fewer than 200,000 people. Later on, the definition was incorporated in the Rare Diseases Act (2002). This definition became binding for all federal states. However, there is a need for a more detailed definition of certain categories of rare diseases that appeared as a consequence of the availability problem of so-called orphan drugs.

In 1962, an amendment (Huyard 2009: 465) to the Food, Drug, and Cosmetics Act prescribed the obligation to provide proof of the efficiency of pharmaceutical products that had been in use since the law was adopted in 1938. This meant that many pharmaceutical products were to be revised or withdrawn from the market (Huyard 2009: 466). The ones labelled 'orphans' – which could be administered in hospital pharmacies – were among these drugs (Huyard 2009: 466). In 1968, as requested by the American Society of Hospital Pharmacists, the Food and Drug Administration (FDA) defined orphan drugs as drugs whose production was strongly limited due to low demand (Huyard 2009: 466). The Orphan Drug Act (1983) included two groups of drugs here: (i) drugs for rare diseases, *i.e.* for diseases affecting fewer than 200,000 people in the USA, and (ii) other drugs that are non-commercial, *i.e.* in the production of which the pharmaceutical industry does not have commercial interests.

At the time the Orphan Drug Act was adopted, patients who had various severe diseases of low incidence joined together to demand that their rights would be guaranteed by the US Constitution and other laws (Huyard 2009: 465). The requests referred to the provision of not only drugs and medical products for treating the diseases, but also for other conditions necessary for those people to completely integrate into the social and working environment. At the time, the basic aim of these organised activities was for people with rare diseases to get fair access to healthcare, education, employment, and social protec-

tion. One should bear in mind that the only similarity among rare diseases is their low incidence and low prevalence, which is why they are called rare. Patients are connected by the need for integration into the social and working environment as much as their disease allows them to.

Historically, rare diseases as a medical phenomenon became more visible thanks to the adoption of the Orphan Drug Act in the USA, which categorised rare diseases as a special group of diseases. Later on, this term became widely accepted in Europe and across the world. Until the late 1970s, the 'rarity of a disorder' was used to mark the characteristics that a doctor was supposed to take into consideration when diagnosing severe diseases, but not as a special category of diseases (Huyard 2009: 464). In the medical literature, rare diseases are not presented as a special category of diseases. Rare diseases appeared as a socio-economic notion *i.e.* a socio-economic category, resulting from the socio-economic needs of certain social groups in the USA in the middle of the 1970s, in the context of the adoption of the Orphan Drug Act. The category of rare diseases was developed in society. It represents the expression of the collective efforts of patients with rare diseases and their family members to regulate their social and legal status.

Determining the concept of rare diseases, their medical classification, and their codification forms the starting point for the legal regulation of patients' personal status. Regulating the legal position of patients with rare diseases and their status from the perspectives of healthcare and labour law requires the adoption of the particular model of classification applied in social and legal discourse. The protection mechanisms of the fundamental social and economic rights of this population could be determined based on the adopted model. For the first time, the Advisory Group for Rare Diseases was established to create the ICD-11 classification model (Robinson 2012: 7). This group's duty is to suggest the comprehensive classification of rare diseases, which will primarily be based upon the clinical principle, as well as on the supplementary poly-hierarchical principle, which would also include those rare diseases that affect multiple organ systems.

At this point, the rare disease registry and classifications of certain rare diseases are presented on the Orphanet portal – the European reference portal that provides the greatest scope of information on rare diseases and the availability of drugs for their treatment. The database contains about 6,000 special forms classified according to published classifications (Robinson 2012: 7). These classification systems are based on scientific foundations: the clinical approach primarily, with the etiological as a secondary factor (Robinson 2012: 7). Orphanet classifications of rare diseases form the basis for classification in the new ICD-11.

The fact that rare diseases are very heterogeneous and complex means it's still difficult to obtain medical classification that can be socially and legally accepted: (i) the exact number of

rare diseases has not been determined; there are between 5,000 and 8,000 rare diseases in the world; (ii) most of them are chronic, progressive, and affect the life expectancy of patients (Heemstra et al. 2009: 1166); (iii) symptoms vary from one type/case to another, but also do so within the same rare disease; (iv) most rare diseases are of genetic origin (80%), but some are caused by infections (bacterial or viral infections) or related to hazards in the patient's living and working environment (European Organization for Rare Diseases 2005); (v) there are diseases that appear as a consequence of autoimmune disorders or allergies; (vi) some rare diseases are of unknown origin (Rinaldi 2005: 507). Eventually, rare diseases represent a grave social problem where the quality of life of the people affected is very poor due to the reduction or complete loss of working capacity, implying that rare diseases have certain consequences on patients' labour status. Having said that, analysing the labour status of people with rare diseases requires classification, which will enable the comprehensive determination of the existing mechanisms for the realisation and protection of social rights, particularly the right to work. On top of this, it means the recognition of people with rare diseases as a vulnerable category of workers with special needs that must be considered in the context of creating national anti-discrimination policies and laws.

THE LABOUR-LAW STATUS OF PEOPLE WITH RARE DISEASES – BASIC ISSUES

From the perspective of labour law, people with rare diseases could be classified based on the criterion of genetic status and its influence on working capacity. The influence of infections as well as patients' living and working environment has not been taken into consideration, since the research question is limited to rare genetic diseases. Also, there is no compiled evidence about the influence of infections or living and working conditions on the emergence of rare diseases.

According to their genetic status and its influence on their working capacity, people with rare genetic diseases could be classified into two different categories: (i) healthy carriers of pathogenic genes and (ii) sick carriers of pathogenic genes. The first category includes those people who have not experienced and who might never experience the manifestation of the disease, who generally have the full capacity to work, who are active, and who are aware of the disease. It also includes people who have experienced the manifestation of the disease, but for whom treatment received immediately at birth or later in life has prevented the further progression of the disease. Thus, they tend to be in a phase of complete remission, which means they have full working capacity in its complete sense.

The second category includes those people whose diseases have manifest-

ed themselves in the form of physical or mental impairments that qualify as a disability. The working capacity of these people depends on the level of their impairment and the type of job they perform. Their working capacity could be limited or they could have full working capacity. Sick carriers of pathogenic genes also include people experiencing the full extent and level of the disease, many of whom cannot work.

Based on the aforementioned classification of people with rare diseases, the legal framework regarding the status of every individual category needs to be determined. Those people who belong to the category of asymptomatic carriers have complete working capacity, while the general regime of labour has to be applied along with the provision of anti-discrimination laws regarding the genetic status of an individual. Genetic discrimination implies discrimination directed against an individual or a family member based solely on an apparent or perceived genetic variation, *i.e.* variation that differs from a normal human genotype (Billings et al. 1992: 476).

The prohibition of genetic discrimination in the field of employment and labour refers to the prohibition of genetic testing as a condition for employment, a condition for promotion, or when deciding to terminate employment, unless such testing is necessary for protecting the health and safety of workers. The worker needs to give informed consent for testing. In cases when genetic testing is justified, there are limitations on the use of genetic information, which means that received genetic information can be used only for the purpose for which consent has been acquired *i.e.* to protect workers' health and safety. The genetic information of an individual is protected under the domain of privacy.

Genetic discrimination in Serbia is generally prohibited by the Law on the Prohibition of Discrimination (2009). Nevertheless, there is no adequate regulation concerning legally allowed or prohibited procedures of genetic testing in the field of employment, *i.e.* labour. Specific regulations for conducting genetic testing in this field have not been adopted. To prevent genetic discrimination, the regulation of genetic testing is essential for the protection of labour rights for workers with a rare heredity disease. This requires uniform standards for the acquisition and disclosure of genetic information – collators of genetic information would have to justify the collection and usage of the information (purpose issue). Governments need to create the mechanism for an independent review of the justification for gathering genetic data (procedure issue), ensure the protection of the worker's autonomy to control personal data (informed consent issue), and provide them the right to review and correct personal data (control issue) (Gostin 1995: 327).

In labour legislation, the conditions for employment can be both general and specific. They refer to a person's ability and qualifications for performing a certain job. General medical ability represents a condition for employment exclusively for jobs with increased health risks (Sorgdrager,

Hulshof and van Dijk 2004: 271). There is a common belief that pre-employment medical examination – which could also include genetic testing aimed at determining someone's ability to perform a certain job – rarely leads to a valid diagnosis. Therefore, there is no relevant evidence for the statement that a person is incapable for work *i.e.* "work capacity is mainly determined by job safety measures and physical demands required for the job rather than on the medical conditions of candidates" (Serra et al. 2007: 309), which consequently shows a growing tendency in labour legislation to indicate the need to abolish pre-employment medical examination as a general condition of employment (Pachman 2009: 530). However, in those legal systems where one's general health capacity is a condition of employment, the determination of whether a person is qualified for a job must be made at the time of employment and cannot be based on predictions regarding the possible manifestation of a disease in the future (predictive genetic testing) *i.e.* in terms of the future health status, because otherwise it shall be considered discrimination (Gostin 1991: 128).

Healthy carriers of pathogenic genes are people with manifested symptoms of a certain rare disease that is under control. The person's disease is in remission and they have the full capacity to work. Still, unlike people who have not had any manifestations of the disease yet, these people are at justifiable risk of that disease recurring, which is why their working conditions should be adjusted to their health status. After a risk assessment in the workplace and medical examinations have been performed, working conditions should be adjusted to the employee's needs, a process that can also include transferring to another job if the current one could cause the recurrence of the disease. In this regard, there is a lack of consensus on the justification of pre-employment medical examinations or periodic examinations of employees, arguing that the evidence demonstrating the efficiency of pre-employment examinations aimed at the prevention of employees' future health risks is unfounded and deficient (Shepherd 1992: 617-621).

Having said that, it is recommended that job seekers/employees should complete medical history forms and, in cooperation with their doctor, *i.e.* occupational health physician, determine the risk factors of the workplace and review any strategies for promoting their health (Pachman 2009: 532). Furthermore, other working conditions should also be adjusted to the employee's health status according to workplace risk. This could imply a reduction in working hours, the provision of longer breaks during working hours, longer vacations, and special paid leave regarding the nature of a rare disease. It is argued that a special labour institute – paid leave for the purpose of therapy for chronic diseases – should be introduced. Employers should also provide these workers with periodic, preventive health examinations to monitor the employee's health status. In Serbia, there are no provisions regarding the special protection of labour rights (special work

conditions regarding vulnerable health status) of workers with chronic diseases, which can include rare diseases.

The working capacity of people with rare diseases who are considered to have disabilities depends on the level of their physical or other impairment and the type of job they are trained for. If their full working capacity is preserved, the general regime of labour relations in terms of employment and working conditions should be applied. However, if their full working capacity is limited, the special regime of the protection of the rights of special categories of employees (*i.e.* people with disabilities) needs to be applied. These people are categorised as having disabilities, and there are special protection regimes in the labour legislation for them. This calls for the application of reasonable accommodation in the workplace, with working conditions that are adjusted to the real needs of people with disabilities in terms of anti-discrimination laws. Discrimination on the grounds of disability is considered to be any distinction, exclusion, or restriction on this basis.

According to the UN Convention on the Rights of Persons with Disabilities (2006), ratified in Serbia in 2009, discrimination also includes unjustified denial of reasonable accommodation (Stein and Lord 2009: 26). According to this Convention, reasonable accommodation means necessary and appropriate modification, not imposing an undue burden for an employer, and ensuring that people with disabilities can exercise all fundamental human rights and freedoms on an equal basis with other employees (Stein and Lord 2009: 26). People with disabilities have the right to adjust existing work facilities to their needs and make them accessible, as well as the right to modifying the work arrangement. This implies the possibility of flexible work arrangements: part-time work schedules, remote work, reassignment to an adequate vacant position, the modification and adjustment of work equipment and devices, the appropriate modification and adjustment of examination papers and training materials, as well as the adjustment of other conditions according to the needs of people with disabilities (Doyle 1993: 97).

For those with rare diseases who have manifestations of the disease to such a level and extent that they are regarded as fully incapable of work, it is necessary to determine the opportunity and availability of exercising their right to social protection.

CONCLUSION

Rare diseases are serious, often chronic and progressive diseases that affect a small percentage of the population. They currently affect between 3.5% and 5.9% of the worldwide population, which equates to an estimated 30 million people in Europe and 300 million worldwide. In Serbia, there is no precise information about the exact number of people affected because there is no register of patients. This impedes the planning system in both healthcare and social security. Despite their great overall number, rare disease patients are the ‘orhpans’ of healthcare systems, often denied diag-

nosis and treatment. Consequently, they find themselves in the vulnerable category of employment and labour.

Regarding the vulnerable status of people with rare diseases, their living conditions and associated problems imply the necessity of being recognised as specially protected workers. Patients' lives are characterised by health difficulties, as a result of which their rights in the field of health seem to be more important than all other related social rights. However, the accomplishment of 'adequate quality of life' for these people and the realisation of the social component of health requires appropriately regulating the labour status of patients suffering from rare diseases. The comprehensive regulation and protection of related social rights including the field of labour, dignity, and non-discrimination issues based on genetic and health information is proposed in developed countries. The right to healthcare and access to services of a certain quality is considered to be a precondition for the realisation of related socio-economic rights, which are of vital importance to them. Sometimes, the status of people with rare diseases in labour legislation is preconditioned by their medico-legal status and, vice versa, their status in labour legislation has an effect on the medico-legal status of patients with rare diseases. This mutual influence should be taken into consideration when we address the area of rare diseases within the legal context. Healthcare and employment/labour conditions should be adjusted to the needs of this vulnerable social group.

Concerning the situation in Serbia, the provisions regarding healthcare and health insurance related to rare diseases have been amended due to patients being neglected by having to wait too long for the right diagnosis, which sometimes leads to the rapid and progressive deterioration of their health. New legislation on rare diseases in Serbian law should be supported through the process of implementation to reduce adverse cases as effectively as possible, advance genetic and other clinical diagnoses, and thus increase the efficiency of available medical treatment.

Concerning public health policy, updated registries and better health statistics should be created. These activities also require certain amendments to general, as well as to special labour legislation (disability legislation) aimed at including patients with rare diseases in the working (and social) environment without discrimination, as well as realising elementary socio-economic rights, primarily the right to (decent) work. Classifying people affected by rare diseases into two categories according to their genetic status and the influence of their disease on their working capacity could represent a legal framework for the future regulation of their labour status, particularly taking into consideration the great heterogeneity of rare diseases, which requires the application of a variety of measures of labour law.

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Radna prava lica sa retkim bolestima – uklanjanje barijera

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SAŽETAK

Lica sa retkim bolestima smatraju se naročito ranjivom kategorijom stanovništva, gde ostvarivanje osnovnih ljudskih prava zahteva utvrđivanje dodatnih mera, uključujući tu i prava na radu i u vezi sa radom. Radna sposobnost ovih lica determinisana je njihovim medicinskim statusom ali i prirodom konkretnog posla, odnosno zavisi od vrste radnih zadataka. Hipoteza rada počiva na povezanosti pojmova – kvaliteta života i opšteg blagostanja sa karakteristikama bolesti što ukazuje na potrebu šireg, odnosno sveobuhvatnog pravnog regulisanja, tj. regulisanja kako medicinskog tako radnopravnog statusa lica koja žive sa nekom retkom bolešću. To znači primenu kako pasivnih mera socijalne politike tako i aktivnih mera politike rada i zapošljavanja sa ciljem unapređenja uslova života i rada, te priznavanje lica obolelih od retkih bolesti kao posebno ranjive kategorije radnika. Regulisanje medicinskopravnog statusa u smislu implementacije postojećih zakonskih odredbi, ali i izrada preciznih registra bolesti, kao i registra lica obolelih od retkih bolesti preduslovi su za regulisanje statusa u radnom zakonodavstvu. S tim u vezi, predložena klasifikacija lica obolelih od retkih bolesti predstavlja osnov za regulisanje radnopravnog statusa ovih lica u domaćem pravu, budući da je zasnovana na holističkom i interdisciplinarnom pristupu, te da ima intenciju da obuhvati što veći broj mogućih slučajeva menifestacije bolesti, s obzirom na karakteristiku značajne heterogenosti i diverziteta ispoljavanja bolesti koje se kvalifikuju kao retke.

KLJUČNE REČI

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