LEGAL FRAMEWORK FOR PROTECTION OF MS PATIENTS’ RIGHTS IN AZERBAIJAN

Multiple sclerosis (MS) is a chronic disease that frequently results in enduring some level of disability. The rights of individuals affected by MS exhibit a nuanced and multifaceted character, extending beyond the purview of purely healthcare legislation. Assistive technologies (ATs) significantly improve the quality of life of that category of patients. To ensure MS patients’ rights, Azerbaijan health law is closely intertwined with disability law and state social security, which also includes ATs provision. The legislation of Azerbaijan in the context of ensuring the rights of MS patients is quite progressive and covers many issues, including the right to get free medicines, ATs, and recreation. The recent inclusion of some medications for MS on the WHO list of essential medicines (EML) creates the basis for further improvement of legislation in the field of treatment of this category of patients. This paper discusses MS treatment and related legislation within the framework of Azerbaijan health law.

Key words: Azerbaijan healthcare, health law, MS patients’ rights, Assistive Technologies (ATs), health insurance.

Introduction

One of the domains of health policy in Azerbaijan concerns the safeguarding of the rights of persons with disabilities. Although this group of people
is considered to be vulnerable, legal protection of their rights, including free access to adequate and quality health care, social support and provision of the employment opportunities, helps ensure higher standards of social protection. Legal frameworks that protect their rights as patients also ensure their dignity, autonomy, well-being, and other human rights. One of such vulnerable groups of patients is those affected by Multiple Sclerosis (MS) and protection of their rights is of high state attention.

Being rare and incurable neurodegenerative condition, MS affects approximately 3 million individuals globally as of 2020 [1]. According to the data as of July 2023, there are 2001 MS patients in Azerbaijan [2] and their number has a tendency to increase annually. The prevalence of MS is rising, and about half of the patients [3] develop some form of disability within 15 years, necessitating the provision of assistive technologies (ATs). In Azerbaijan, the law ‘On state care for people with multiple sclerosis’ covers their treatment. Additionally, the provision of ATs to MS patients as well as other social benefits are covered by the relevant general provisions applicable to people with disabilities.

MS Patients’ medical rights primarily cover access to appropriate medications. Thus, the first medication for MS in the world was registered in 1993 [4], and in recent years the number of drugs has increased markedly, providing a wide range of treatment options for patients. However, MS Treatments were added to the List of Essential Medicines (LEM) by the WHO only in 2023 [5]. This opens up new opportunities for improving medical rights of patients with MS since the healthcare systems of WHO member states are guided by the decisions of the organization, accordingly improving legislation in this direction.

The objective of this research is to analyse the existing legal norms of the Republic of Azerbaijan (AR) regarding the protection of the rights of MS patients, the legal regulation of their treatment, and the provision of ATs, which are recognized as an essential component of the national health law. A corresponding analysis of the relevant legislation was carried out. Also, relevant updates in the context of treating those patients were noted and prospects for further improvement of legislation were considered.

**MS patients’ rights in Azerbaijan legislation**

The treatment of MS patients is covered in a series of legislative enactments. These include the ‘Law on Protection of Health of Population,’ (or Law on Public Health) adopted in 1997. General patients’ rights in AR are safeguarded by Article 24 of the 1997 Law. While this law does not explicitly differentiate between patient categories or reference the term «chronic (incurable) illness,» it does incorporate article 21, which emphasizes the provision of medical assistance to persons with disabilities, which is applicable to MS patients too.

The legislative framework for the treatment of MS patients in Azerbaijan has been evolving since 2012, when the AR Law ‘On state care for people
with multiple sclerosis’ (hereinafter MS Law) was enacted [6]. This law established the rights and obligations of MS patients, as well as the responsibilities of the state and other entities in providing medical and social assistance to them. According to the MS Law (art. 2), in addition to the national legislation, including the Constitution and ‘Law on Public Health’, state care for people with MS consists also ‘of international agreements’ that the AR has joined [7]. This ensures the study of international experience and its adaptation in the country.

AR MS Law of 2012 in its article 7 confirms detailed rights of affected people. The article consists of eight paragraphs, which include the provision of highly effective injection tools and other medicines, the list of which is determined by the relevant executive authority, the right to stay in a hospital for the necessary time for examination and treatment, free psychological assistance, etc. Moreover, the law prohibits refusal to conclude an employment contract or termination of an employment contract due to the presence of MS in a person. This provision is a clear confirmation of the progressiveness of the legislation in relation to the prevention of discrimination and protection of social rights.

Some normative legal acts that expanded the standards of MS treatment followed the enactment of the 2012 Law, such as the AR Cabinet of Ministers (CoM) Decision No. 278 on December 5, 2012, which established ‘The procedure for financing the examination and treatment of people with multiple sclerosis in state medical institutions’ and defined ‘Scope and quality standards of medical care for people with multiple sclerosis’ [8]. The AR CoM Decision No. 211 of September 25, 2012, approved the annual amount of medical assistance (including necessary examinations), the types and quantities of injectables and other medications provided to the MS patients [9]. The services covered by these Decisions comprise consultations with a neurologist, an ophthalmologist and a physician, MRI, plasmapheresis, blood tests, etc.

With the adoption of mentioned-earlier legislation, intensive work on coordinating the treatment of this category of patients has begun. To some extent, their treatment was specialised from the general medical legislation. A special department was launched under the Republican Clinical Hospital named after Acad. M.A. Mirgasimov. That was very important in terms of ensuring the patients’ rights as their treatment has become more centralised, and their records have begun to be collected. Centralised treatment and monitoring had their advantages since patients were confident that there was an institution where they could apply and register for free medicines. However, this also created some difficulties. Since residents living in the regions often had to come to the capital to receive qualified assistance and appropriate registration. Moreover, in the 90s and early 2000s, the MRI machines needed to clarify the diagnosis were rare counting several ones in the country. Therefore, to confirm the diagnosis, patients had to travel to the capital region.

To operationalize the provisions of the MS Law, several ‘State Programs on the treatment, prevention and control measures of multiple sclerosis’ were approved by the Presidential Decrees. Thus, in 2012 the Program covering the
years 2013-2017 and in 2018 covering the years 2018-2022, respectively [10, 11]. These programs outlined the strategic goals, objectives, activities, indicators and funding sources for addressing the challenges faced by MS patients in Azerbaijan.

The 2018 program was essentially a continuation of that from 2012, but it had its own peculiarities. Thus, it briefly outlined some of the successes of the first program, including that as a result of its application, important steps have been taken in the direction of strengthening the material and technical base of medical institutions dealing with the treatment of these patients, equipping diagnostic laboratories with modern equipment and reagents, providing patients with specific medicinal preparations, training personnel for this field, and extensive conducting educational work among the population. As a result, the detection of the disease has improved, and the number of complications has decreased. Moreover, the goals of the 2018 Program were supplemented by provisions on the organization of recovery treatment. Also, the expected results were expanded to include «improvement of diagnostic work» and «prevention of complications».

The provision of medical assistance to persons with disabilities, including MS patients, is also regulated by the AR Law ‘On the Rights of Persons with Disabilities’ adopted in 2018 [12]. The adoption of this Law opened a new page in the issue of protecting patients’ rights with disabilities. Thus, this Law consists of 40 articles covering the parameters of the definition of disability, the basic principles of state policy to protect the rights of people with disabilities, state support, their rehabilitation, personal development, including education, etc. It is worth noting that the first AR law on the rights of persons with disabilities was adopted back in 1992 and was called «On the prevention of disability and children’s health disabilities, rehabilitation and social protection of disabled children and children with health disabilities.» However, with the entry into force of the 2018 Law, the 1992 Law became invalid. The new Law of 2018 was adopted with a more detailed account of modern trends in global legal practice and standards proclaimed within international organizations such as WHO.

The development of healthcare legislation in Azerbaijan was further stimulated by the introduction of universal health insurance, which aimed to improve the accessibility and quality of healthcare services for the population. AR Law on Health Insurance was adopted in 2018 but due to technical issues, including transformation of health sector, and further complications caused by the COVID-19 pandemic, its implementation has been postponed and it came into force only in 2020 [13]. After its introduction the treatment of all citizens had to take place in medical institutions at the place of their registration. That is, if earlier there was a process of centralisation – the tendency of all patients to visit and get treatment in the capital, after 2020 the reverse process has begun, although patients still have the right to seek medical help in the hospitals of place of residence.
In the first months of the introduction of insurance, some difficulties arose with the treatment of patients living in a region different from the place of registration. However, today this issue has been resolved. It has now been clarified that every insured person, including MS patients, can receive treatment not only at the place of registration but also at the place of residence, by registering with the appropriate medical institution (called polyclinic in Azerbaijan).

At an early stage of the introduction of insurance, for example, for treatment in Baku (the capital), a citizen was required to obtain an appropriate referral from a doctor at his place of residence; now that standard has been cancelled.

According to the Decision of the AR Cabinet of Ministers On approving the ‘Package of Services for Mandatory Health Insurance’ adopted in 2020 [14], emergency and urgent medical care, including in outpatient and inpatient settings in cases requiring urgent medical intervention, also includes ‘exacerbation of chronic diseases.’ MS is a chronic disease characterised by the possibility of sudden worsening of the condition, i.e., exacerbation. With regard to the insurance the MS law (art. 5) clarifies that measures for the examination and treatment of people with MS are funded by the state and can be also provided at the expense of municipal and mandatory health insurance funds, as well as other funds provided by legislation.

The services provided under the insurance and their payment are reflected in the relevant ‘Benefits Package’, which is available for both insured and uninsured persons [15-16]. The list of medical services covered under mandatory health insurance [17] reflects the information about the cost of treatment of certain health-related events with regard to the ‘chronical’ diseases. Thus, it includes organising periodic examinations of patients for the purpose of managing chronic diseases and providing appropriate advice, treatment and monitoring in cases that do not require qualified intervention for the purpose of early detection of exacerbation of the chronic diseases etc. Art.15-2 (insured under mandatory health insurance), of the Insurance Law notes that its basic package covers all citizens of the country, while the additional part of the package of services includes persons who are unable to work. Therefore, as MS is a chronic disease in most cases leading to disability, MS patients fall under both categories.

It is worth noting that, in accordance with the Insurance Law, if a patient requires a procedure that is not offered in the public hospital where he is registered, with a doctor’s referral, this procedure can be performed in a private clinic, which will be covered by insurance. This is especially relevant in the context of diagnosing patients with MS, since MRI machines are not available in all hospitals.

**Extension of Social Protection as part of MS patients’ rights**

The rights of MS patients were enshrined as a separate clause in the Labour Code of the country [18], in accordance with the amendment of 2009
(art. 79.1), as well as with the amendments of 2012 (art. 16.1), which approved a prohibition of the refusing to conclude a labour contract or its termination due to the illness. According to the updates of 2012 made to the Decision of the AR Cabinet of Ministers On the approval of ‘Regulation on the calculation and payment of compulsory state social insurance payments and allowances paid at the expense of the insurer to employees who have temporarily lost their ability to work’ (art. 62) [19], in case of temporary loss of working capacity due to the MS, the allowance is given in the amount of 100 per cent of the earnings. We consider this provision progressive and broadly protecting the rights of patients. AR Code of Administrative Offenses [20] approved in 2015 (art. 192.11) also mentions the disease and confirms the provisions of the Labour Code.

One of the recent legislative changes in the context of social protection of MS patients was approved on May 13, 2022 [21]. Thus, in accordance with the amendments to the MS Law, patients’ social protection was expanded and they, in addition to the social benefit, received the right to and (or) receive a labour pension. It should be noted that the national Labour legislation (art. 7) requires at least ‘25 years of insurance experience’ to get the determination of labour pension [22], which quite often becomes impossible due to the MS-related acquired disability. Thus, the rights of this category of persons were significantly expanded, since previously they were only entitled to social benefits (disability allowance), which are often lower than labour pensions. So, protection of MS patients’ social rights is improving.

**MS patients’ treatment developments and WHO decision**

The recent WHO decision to expand the list of Model Lists of Essential Medicines (EML) creates a platform to improve treatment and protect the health of patients with MS. Thus, according to the WHO three medicines – cladribine, glatiramer acetate and rituximab – were added to the EML, «filling an important gap given the large global burden of MS» [23].

At the moment, unfortunately, none of the mentioned medicines is registered in Azerbaijan, which creates certain difficulties in obtaining them or the need to seek treatment abroad. However, on July 14, 2023, certain amendments were made to the AR Law on Medicines [24, 25], which facilitated their independent purchase by MS patients. That amendment applies to all medicines and now it will be possible to freely import medicines from abroad for personal use based on a prescription. At the same time, drugs written on an approved prescription, which are not included in the state register, can be brought to the country only in the amount written in the prescription by wholesale pharmaceutical enterprises, pharmacy organizations or the body (institution) determined by the relevant executive authority based on the patient’s needs. The sale of these medicinal products is prohibited in the country, except to the person who was prescribed it.
Доктрина медичного права

According to the amendment mentioned earlier, a drug that is considered necessary for the treatment of patients according to clinical protocols, but is not state-registered with its international non-patented name (name of the active substance), can be written in the prescription. In this case, the prescription is submitted to the body (institution) determined by the relevant executive authority through the system, indicating the required amount of the drug. Within 2 (two) working days, the body (institution) determined by the relevant executive authority checks the compliance of the prescription with the clinical protocols and the information in the patient’s electronic health card and approves or rejects the approval of the prescription in the electronic system according to the results. After the prescription is approved by the body (institution) determined by the relevant executive power body, the medicinal product specified in the prescription, which is not state-registered, can be brought into the country.

**Assistive Technologies as a patient right**

The right to receive ATs applies to all categories of people with disabilities in accordance with the AR Law on the Rights of Persons with Disabilities. However, there is no strategic plan for rehabilitation of MS patients. The decision of AR CoM On approval of the ‘Regulation on the preparation, approval and implementation of the Individual Rehabilitation Program’ was adopted in 2020 [26]; it also does not specify MS patients. However, according to the Regulation (art. 1.2), the individual program includes complex measures related to the medical, professional labour, psychological-pedagogical rehabilitation and development of social skills of a person with a disability. Implementation of the individual program is conducted by the state bodies and state-owned legal entities. However, despite the presence of a wide network of state rehabilitation centres in the country, unfortunately, there is none aimed specifically at the rehabilitation of patients with MS. Private clinics and centres offering rehabilitation for MS typically suggest measures used for other medical conditions, such as stroke or just general neurology.

The Ministry of Labour and Social Protection of Population (MOLSPPP) possesses a dedicated institutional entity responsible for overseeing the administration of rehabilitation and ATs, referred to as the State Medical-Social Expertise and Rehabilitation Agency abbreviated as DTSERA [27]. It has a disability-friendly website providing many services, including the possibility to register for an appointment online. Although the Agency maintains general statistics on people with disabilities, precise statistics on rehabilitation or provision of AT for patients with MS are limited or completely absent. The MOH and MOLSPPP each maintain specific focal points devoted to the realm of rehabilitation. Although additional ministries may partake in rehabilitation-related initiatives, a unifying framework or mechanism for the exchange and deliberation of rehabilitation-related subjects is absent.
**MS clinical trials as a missing issue**

An important component of healthcare is conducting medical research. Since there is no state MS Center in the country and the official website of the MS society, the information about the disease for patients is fragmented. Therefore, in order to educate patients about their rights and opportunities provided by law, it is important to conduct legal training for medical personnel.

The National Association of Neurologists’ website [28] does not reflect information about ongoing clinical trials on MS. The e-library section of the website (as of September 8, 2023) is empty. Although an international conference on MS was held in June 2023, information about the materials presented at it is not available. For example, the European Committee for Treatment and Research in MS (ECTRIMS), the US MS Society, the UK MS Society etc. not only fund a large number of studies but also publish their results on their official website. Thus, ECTRIMS [29] also provides some fellowship programs for researchers and includes learning resources. Unfortunately, not all MS patients are qualified to self-study innovative treatments. Moreover, the language barrier also matters. For example, the MS Association in Türkiye [30] has a very informative website reflecting information about phone numbers, where patients can call for questions, activity reports, etc.

Google search (as of 08.09.23) for the ‘research on multiple sclerosis in Azerbaijan’ (Aze. ‘Azerbaiycanda dağınıq skleroz üzrə tədqiqat’) words’ combination [31] returns no exact results with only related general information about the disease. In relation to the patients’ rights, the results provide references to official laws. However, it is not always possible to understand it without specialised legal advice. Such a lack of an online platform is extremely undesirable from the point of view of the patient’s psychological balance and the right to information. Doctors themselves, as a rule, answer patient’s questions extremely reluctantly, operating on the fact that the disease is incurable. Nevertheless, the patient, even in the presence of such a diagnosis has the right to get information about the disease, its treatment options and possible outcomes.

**Conclusion**

The inclusion of MS medicines in the WHO EML has become an important signal that increases attention to the treatment of this group of patients worldwide. Unfortunately, available data indicate an increase in the number of patients with this disease [33]. This is also relevant for Azerbaijan. If at the beginning of 2000, the number of MS patients did not reach 1000 people, now it exceeds 2 thousand. Accordingly, their protection requires attention from the state and relevant legislation updates.

Although the number of MS patients in Azerbaijan is small, this category of patients is quite vulnerable, as the disease leads to disability. Protecting the rights of patients with disabilities is a complex topic. In the context of this
work, we have covered the rights of MS patients related to treatment, work and rehabilitation. The introduction of health insurance in Azerbaijan at the first stage created certain difficulties. However, today they have already been eliminated. Legislation regarding MS patients is developing and covers not only the medical field. Patients with MS are provided with ATs; with the recent legislation update, purchasing medicines abroad has become more accessible.

From the point of view of legislation, there is both social and medical protection of the patient’s rights. However, there is an urgent need to establish legal standards of rehabilitation for MS patients. More research on MS medicines and legal education of professionals is also needed.


19. Information and Communication Technologies Department of the Ministry of Justice, ‘Regulation on the calculation and payment of compulsory state social insurance payments and allowances paid at the expense of the insurer to employees who have temporarily lost their ability to work’. Retrieved 28 December 2022, https://e-qanun.az/framework/3468#_ednref2 (in Azerbaijani).


23. supra note 5.


Права осіб, уражених розсіяним склерозом, і допоміжні технології в Азербайджані

Розсіяний склероз (РС) є хронічним захворюванням, яке часто призводить до тривалої втрати працездатності. Права осіб, уражених РС, мають нюанси та багатогранність, виходячи за межі виключно законодавства про охорону здоров’я. Допоміжні технології (ДТ) значно поліпшують якість життя цієї категорії пацієнтів. На забезпечення прав пацієнтів, хворих на РС, в Азербайджані спрямоване законодавство про охорону здоров’я, законодавство про інвалідність і державне соціальне забезпечення. Вони охоплюють багато питань, включаючи право на безкоштовне отримання ліків, ДТ, відпочинок. Нещодавне включення деяких препаратів від РС до Переліку основних лікарських засобів (ЕМЛ) ВОЗ створило підґрунтя для вдосконалення законодавства і поліпшення лікування цієї категорії пацієнтів.

Ключові слова: охорона здоров’я Азербайджану, законодавство про охорону здоров’я, права пацієнтів з розсіяним склерозом, допоміжні технології, медичне страхування.

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