

Resource on the State of the Art of Rare Disease Activities

2025 Report for Serbia

National Mirror Group

Serbia has a National Mirror Group (NMG) for rare disease, which was launched on 28th May 2025. The NMG is coordinated by the Institute of Molecular Genetics and Genetic Engineering (IMGGE). This NMG has overseen the collection of data from Serbia via a data contributing committee. Contributors are listed at the end of this report.

Definition of a Rare Disease

Serbia adopts the formal European Union (EU) definition of a rare disease (i.e. those with a prevalence of no more than 5 patients per 10,000 persons. This definition is laid down in Regulation EC no. 141/2000 on Orphan Medicinal Products, Directive 2011/24/EU on Cross Border Healthcare as well as in the Council Recommendation on an action in the field of rare diseases of 8 June 2009). The national plan espouses this definition and there are no instances where a different definition is used.

Status Quo of any National Plan or Strategy for Rare Disease

What is the status quo?

Serbia does not currently have a live or in-date National Plan for Rare Disease. [The National Program for Rare Diseases in the Republic of Serbia](#) was adopted in December 2019 and was active between 2020 and 2022 but has now expired. The program was monitored by a working group set up by the Ministry of Health of Serbia.

Patient organisations in Serbia, including the National Organisation for Rare Diseases of Serbia (NORBS), are actively engaged in advocacy efforts aimed at adopting a new National Program for Rare Diseases. These advocacy initiatives are directed toward key decision-makers at the national level. To date, several consultative meetings have been held with representatives of the Ministry of Health, the Ministry of Social Affairs, the Ministry of Family Welfare and Demography, and the Institute of Public Health of Serbia. All stakeholders are in consensus on the need to adopt a new National Program, by evaluating the outcomes and identifying unmet priorities from the previous program, but this has not yet been carried out. The development, formal adoption, and full implementation of a new and updated

National Program for Rare Diseases is needed. This is essential to address the evolving challenges faced by the rare disease community in Serbia in various sectors, including healthcare, social security and education.

Elaboration and Adoption/How was the original plan elaborated?

For many years, patient organisations in Serbia have been actively advocating for the development and adoption of a national strategy or program for rare diseases. These efforts focused on raising public awareness, sharing knowledge, and encouraging decision-makers to become actively involved.

As a result of the collaborative efforts between NORBS, Health Care Professionals, and relevant national institutions, Serbia's first National Program for Rare Diseases was developed. This process was driven by a shared recognition of the unmet needs of the rare disease community and the importance of systemic support. The program was adopted by the Serbian government in 2019 as an official policy document and included in the framework of national health planning.

Renewed efforts are currently underway to draft a new program that would be better integrated and connected to other regulatory documents, based on experiences with the previous program.

The previous program for rare disease had a dedicated group in charge of drafting and the adoption of the program. This group included representatives from the Ministry of Health and representatives from the competent national authority in charge of social affairs, relevant medical experts and representatives of patient organisations (namely Serbia's National Alliance).

Is there funding for the strategy? How is it Implemented and/or Monitored or Evaluated?

A different group was set up with the responsibility of implementing and overseeing Serbia's National Programme for Rare Disease. This group included representatives from Serbia's competent national authority including health and social affairs, researchers, people with a lived experience of a rare disease and clinicians. The programme has now expired but when in place the group responsible for implementing and overseeing the programme met infrequently. No formal evaluation of the previous program for rare disease has taken place yet. There were no funding or resources committed to the previous program itself but there was budget dedicated to actions within the program.

Research in National Plans or national research strategies relevant to rare disease

The previous National Programme for Rare Disease for Serbia has now expired but it did not address rare disease research. The program was more focussed on diagnostics, treatment and social aspects.

The program did promote alignment with international initiatives such as Orphanet. The National Program specifically addressed the following topics:

- Registries or registry catalogues for rare diseases
- Ontologies, codification or data standardisation
- Diagnostics research ('solving unknown conditions')
- Sociological (e.g. Quality-of-Life-related) or socio-economic research

Serbia's National Program for Rare Disease was designed to complement broader national health priorities, with a particular focus on improving access to diagnostics, treatment, and integrated care. Whilst the program was not formally aligned with specific national strategies, it did address several cross-cutting areas relevant to other health initiatives.

There were no specific plans for collaboration with other countries outlined within the 2020-2022 National Program for Rare Disease. However, the French and Croatian programmes were used as models/inspiration by the patients' organisation NORBS.

Select achievements resulting from the National Program for Rare Disease

Below are four achievements resulting from Serbia's national program for rare disease:

1. **Establishment of a Rare Disease Registry:** One of the key measures was the development of a national registry for rare diseases, enabling more systematic data collection and improving the basis for epidemiological monitoring and healthcare planning. The registry is currently in its initial recruitment phase.
2. **Strengthening Collaboration Between Stakeholders:** By establishing the Working Group for monitoring and coordination of the implementation of the National Program for rare diseases The program fostered stronger collaboration between patient organisations, healthcare professionals, academic institutions, and government bodies, creating a more coordinated approach to addressing rare diseases.
3. **Adoption of the Definition of Rare Diseases into National Documents:** The National Program introduced for the first time an official working definition of rare diseases (fewer than 5 in 10,000 people), harmonised with the EU definition. This definition was incorporated into the National Program.
4. **Designation and Expansion of Tertiary-Level Centres for Rare Diseases:** Through a formal ministerial decision, a group of 14 clinics were designated to serve as Centres for Rare Diseases.

Rare Disease Research Programmes and Funding

There are no rare disease specific funding programmes/calls in Serbia but rare disease projects are funded through general research programmes.

Rare Disease Registration and Biobanking

Serbia has a national registry for rare disease. The Institute of Public Health of Serbia is responsible for maintaining the Registry of Persons Affected by Rare Diseases for Serbia. Since September 2021, through the Public Health Service Information System, the Institute of Public Health of Serbia has enabled the entry of data on patients with rare diseases. Patients are registered into designated university reference centres immediately after diagnosis.

According to the Law on Health Care, designated rare disease centres maintain disease-specific registries. All healthcare institutions in Serbia (primary healthcare centres, hospitals, clinical centres, and clinical-hospital centres) are obliged to submit data on patients with rare diseases to the designated reference centres. Data from the registries maintained by rare disease centres are subsequently transferred to the National Rare Disease Registry managed by the Institute of Public Health of Serbia. The process of collecting and entering data on newly diagnosed, affected, and treated patients with rare diseases into the Registry is continuous. As of 14 February 2025, healthcare institutions in Serbia registered 14,528 individuals into the Rare Disease Registry through the Public Health Service Information System. Further information can be found [here](#).

The registry uses Orphacode and ICD-10 coding systems. Common Data Elements for rare disease registries, recommended by the European Commission through the European Platform on Rare Disease Registration (EU RD Platform), are collected within Serbia's national rare disease registry.

There are several national disease-specific registries in Serbia but they are not always updated. There is no group tracking or monitoring which rare disease specific registries are available. There is no defined and continuous support for these registries.

There is no national biorepository for rare disease biosamples in Serbia but there are individual biorepositories for rare disease biosamples.

Organisation of Rare Disease Care

Centres of Expertise

There is a national policy in place for designating Centres of Expertise (CE) in rare disease in Serbia. The Serbian Ministry of Health designated six centres as CEs, who coordinate with hospital and clinics. It was agreed that the designation criteria for CEs needed to be refined in order to identify and accredit hospital units with a specific expertise on a group of rare pathologies. The CEs, once designated, should be financially supported to provide good care and join European Reference Networks, in the future. The criteria for designating CE for rare disease includes the following requirements (based on the 2011 EUCERD Criteria for CEs):

- Contribute to state-of-the-art research
- Bring together, or coordinate, multidisciplinary specialised medical and paramedical expertise such as physiotherapists, speech therapists, dieticians, genetic counsellors, etc
- Participate in data collection for clinical research and public health purposes

Newborn Screening

Four conditions are included within Serbia's Newborn Screening Programme: phenylketonuria, congenital hypothyroidism, cystic fibrosis and spinal muscular atrophy. The Ministry of Health and the Commission of the Republic Health Insurance Fund for the treatment of rare diseases make decisions

about conditions to be included within the newborn new screening programme. Research organisations and tertiary medical institutions can make applications for conditions to be considered for inclusion in the programme.

Diagnostics

The majority of laboratories that carry out genetic testing are located in healthcare institutions in Serbia. IMGGE and the Faculty of Biology are academic institutions that have a contract with the Republic Health Insurance Fund for Serbia to conduct genetic testing for rare diseases. Genetic testing, including Next Generation Sequencing (NGS), is covered by the Republic Health Insurance Fund for all patients suspected to have a rare disease.

Zoe's Law (the Law on the Prevention and Diagnosis of Genetic Diseases, Genetically Conditioned Anomalies and Rare Diseases) is a regulation in the Serbia that legally obliges physicians to send a patient's samples abroad, at the expense of the state, if they are unable to establish a diagnosis within six months. The law was adopted in January 2015. If international expertise is necessary, the Commission of the Republic Health Insurance Fund for the treatment of rare diseases makes decisions about sending samples to European reference laboratories for Whole Genome Sequencing (WGS) analysis.

Serbia is involved in a European Union funded project to address undiagnosed patients/people with currently undiagnosable conditions named BRIDGING-RD (BRIDGing the research and INnovation Gap for Rare Diseases in Europe by upgrading excellence of IMGGE). One of the project's main objectives is to capture and reanalyse samples of people suspected of having a rare disease who currently have no diagnosis.

There is a policy in place to ensure that national providers provide genetic counselling for patients with a suspected or confirmed rare disease.

National Alliances of Rare Disease Patient Organisations

Serbia's National Alliance of rare disease patient organisations is the National Organization for Rare Diseases of Serbia (NORBS). Further information about NORBS can be found [here](#). NORBS is involved in the Serbian National Mirror Group (NMG). NORBS is not currently involved in setting the strategic direction for research for rare disease in Serbia, as this is not part of the mission of NORBS. Additionally, there are a lack of opportunities to be involved and insufficient resources. NORBS does provide webinars and other forms of learning and capacity-building on patient engagement in rare disease research, as well as conducting surveys amongst members about engagement in rare disease research.

Information Resources for Rare Disease

National Orphanet Engagement

There is an operational Orphanet team in Serbia hosted by the institute of Molecular Genetics and Genetic Engineering, University of Belgrade. The team does not receive funding and works on a voluntary basis. The Serbian National Orphanet team ensures that national resources such as expert centres, patient organizations and rare disease research projects are included within the central Orphanet database. Prioritisation of resources to be collected is decided at the beginning of each calendar year.

Helplines

There is a national rare disease helpline provided by NORBS for patients. The helpline receives a mixture of public and private funding. NORBS provides support, advocacy, and information for patients and families.

Training and Education

There are rare disease training activities available in Serbia. Training is organised by academic institutions, health institutions and patient organizations. Training is usually accredited as a continual medical education symposia or course. Topics included in these training activities are diagnostics, awareness raising of rare disease, registries and clinical research. Trainings are mostly dedicated to patients and their families, but also to clinicians, geneticists and other medical professionals. Training provided is generally free and available in the Serbian language.

Education about rare diseases is available within higher education in Serbia as a part of many courses at the Faculty of Medicine and Faculty of Biology, University of Belgrade, University of Novi Sad and University of Niš. However, there is no course or curricula that is specifically and fully dedicated to rare diseases.

Orphan Medicinal Products (OMPs)

In Serbia, the Republic National Health Insurance fund (NHIF) funds and provides access to innovative medicines. The number of diagnoses for which the state provides medication is 40. The number of OMPs available in Serbia is continuously increasing.

There are currently no early access or expanded access programmes within Serbia.

The budget for rare diseases in Serbia has been continuously increasing since its establishment in 2013 and has now reached 10.2 billion dinars, which is considerably more than when the budget was established 12 years ago. This budget growth has enabled an increasing number of people, currently 930 patients up from eight initially, to be treated. Medication for spinal muscular atrophy is provided in

Serbia at the expense of compulsory health insurance. The budget for rare diseases is not the only source of financing, as rare diseases are also treated through medicines on the drug list and medication outside the list procured by healthcare institutions. As a result, the total funds are significantly higher, amounting to 20 billion dinars last year.

Patients may also be approved for a therapy that is not registered in Serbia. In such cases, they do not wait for the medicine to be registered in our country. Immediately upon the drug's registration with the European Medicines Agency or the US Food and Drug Administration, patients receive the therapy.



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The Data Contributing Committee of Serbia, which provided this 2026 data (correct as of the end of May 2026) in the context of the Resource on the State of the Art of Rare Disease Activities, is composed of the following individuals:

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