

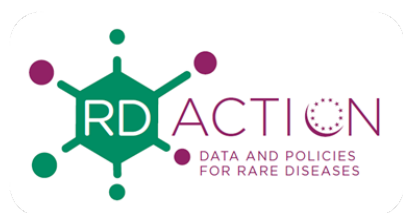
*Serbia*

**EUROPLAN NATIONAL CONFERENCE**

*in the framework of the EU Joint Action RD-ACTION*

*Belgrade, 08-09 November 2017*

**FINAL REPORT**



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# FOREWORD

The EUROPLAN national conferences or workshops are organised in many European countries as part of a coordinated and joint European effort to foster the development of comprehensive National Plans or Strategies for Rare Diseases addressing the unmet needs of patients living with a rare disease in Europe.

These National Plans and Strategies are intended to implement concrete national measures in key areas from research to codification of rare diseases, diagnosis, care and treatments as well as adapted social services for rare disease patients while integrating EU policies.

The EUROPLAN national conferences/ workshops are jointly organised in each country by a National Alliance of rare disease patients' organisations and EURORDIS–Rare Diseases Europe. **Rare Disease National Alliances and Patient Organisations have a crucial role to shape the national policies for rare diseases.**

The strength of EUROPLAN national conference/ workshop lies in its shared philosophy and format:

- **Patient-led:** National Alliances are in the best position to address patients' needs;
- **Multi-stakeholders:** National Alliances ensure to invite all stakeholders involved for a broad debate;
- **Integrating both the national and European approach to rare disease policy;**
- **Being part of an overarching European action** (project or Joint Action) that provides the legitimacy and the framework for the organisation of EUROPLAN national conferences/workshops;
- **Helping national authorities adhere to the obligations stemming from the Council Recommendation of 8 June 2009 on an action in the field of rare diseases.**

Since 2008, National Alliances and EURORDIS have been involved in promoting the adoption and implementation of National Plans and Strategies for rare diseases. Altogether, 30 EUROPLAN national conferences took place in the framework of the first EUROPLAN project (2008-2011) and the EU Joint Action of the European Committee of Experts on Rare Diseases – EUCERD - (2012-2015).

Within RD-ACTION (2015-2018), the second EU Joint Action for rare diseases, National Alliances and EURORDIS continue to get involved in a coordinated European effort to advocate for and promote integrated national policy measures that have an impact on the lives of people living with rare diseases.

The EUROPLAN national conferences or workshops taking place within RD-ACTION focus on specific themes identified by the National Alliances as the most pressing priorities to tackle with national authorities. These thematic priorities are addressed in sessions where all the stakeholders discuss relevant measures to be taken or ways to sustain the full implementation of already approved measures.

Each National Alliance prepares a final report on the national workshop, based on a common format such as the one that follows.

## GENERAL INFORMATION

<b>Country</b>	Serbia
<b>National Alliance (Organiser)</b>	National Organisation for Rare Diseases of Serbia
<b>Date &amp; place of the national workshop/conference</b>	08-09/11/2017
<b>Website</b>	www.norbs.rs
<b>Members of the Steering Committee</b>	Davor Duboka, NORBS Executive Director Dragana Miletić Lajko, NORBS President Ivana Badnjarević, NORBS Vice President
<b>List of Themes addressed</b>	1. Centres of Expertise for Rare Diseases 2. Improving Access to RD Treatment 3. Specialised Social Services for PLWRD
<b>Annexes :</b>	I. Programme in English II. List of Participants (by stakeholders' categories)

## FINAL REPORT

### I. Introduction/ Plenary session

- On the 8 and 9 November 2017, NORBS successfully organised the Serbian EUROPLAN conference. Conference venue for the first day of the conference was a lecture hall at the Serbian Chamber of Commerce. Invitations were sent to all the relevant institutions, patient organisations, physicians, researchers, as well as the pharmaceutical industry representatives and the media. In total, more than 80 attendees were present, including representatives of all the relevant institutions: Ministry of Health, Ministry of Social Welfare and Serbian Health Insurance Fund. Some of the key messages of the plenary sessions were as follows:
  - o State Secretary at the Ministry of Health, Dr. Meho Mahmutović stated that the Ministry recognises the challenges of rare diseases and that it is continuously working on improving the status of People Living With Rare Disease (PLWRD) in Serbia, both through providing adequate funding for rare disease treatments and through working on drafting and adopting the National Strategy for Rare Diseases, which is planned to be adopted by end of 2017.
  - o Acting director of the Serbian Health Insurance Fund Dr. Verica Lazić explained that the Fund is providing not only treatments for PLWRD, but also medical devices and is paying for diagnostic procedures abroad.
  - o Ministry of Social Welfare representative Ms. Biljana Barošević stated that this Ministry is aware of the problems faced by PLWRD and is trying to provide adequate support to this group.

- NORBS Executive Director Mr. Davor Duboka announced the key themes of the conference, and also stated that the reasoning behind this EUROPLAN conference is that, in Serbia, we still do not know enough about rare diseases and not enough has been done for PLWRD. He also stated that this EUROPLAN conference is a call for discussion to all the stakeholders, in order to: improve the designation process of Centres of Expertise (CEs), access to treatment and access to Specialised Social Services for PLWRD in Serbia.

## II. Themes

### THEME 1 - CENTRES OF EXPERTISE FOR RARE DISEASES

#### - Identification of specific gaps, challenges and needs:

In early 2014, Serbian Ministry of Health designated first four Centres of Expertise for Rare Diseases, followed by another designation in early 2015. However, these CEs were designated very broadly, i.e. the whole Clinical Centre of Serbia in Belgrade, in itself consisting of more than 20 clinics was one of the designated CEs. This proved to be a huge organisational challenge, and in the past three years no progress has been made in terms of mapping of appropriate expertise inside these huge tertiary level healthcare institutions.

Trying to address and overcome these challenges, the Ministry of Health Task Force tasked with drafting of the National Strategy for Rare Diseases in Serbia proposed a set of recommendations for designating Centres of Expertise, in line with the criteria outlined by the European Union Expert Committee on Rare Diseases (EUCERD). As the National Strategy is nearing its completion and adoption, it was deemed necessary to have an open discussion on the future designation model of CEs in Serbia and the challenges faced when implementing these recommendations.

#### - Assessment of the integration of European guidelines and policy recommendations into the national system:

Ms. Victoria Hedley of Newcastle University and RD-ACTION (the Joint Action for Rare Diseases) presented on the EUCERD Recommendations on quality criteria for CEs for Rare Diseases (RDs), outlining the need for a concrete set of criteria (as far as possible comparable between countries). These criteria include the need to ensure a multidisciplinary approach, encompassing not only the various medical specialists required to diagnose, treat and care for patients with complex conditions, but also facilitate integrated care (which for rare disease often entails also paramedical, psychosocial and social support: to be truly expert in RD, a CE should consider the broader holistic needs of patients and work closely with other local actors and services to deliver this 'joined-up' approach). However, it was noted that not all of the criteria need to be fulfilled at once, since designation of CEs should be a process adapted to the real world situation in countries. Victoria emphasised the need to designate CEs at the level of diseases/groups of diseases (e.g. Neuromuscular, rare renal etc.): this offers several advantages, such as the ability to ensure a 'critical mass' of patients attend a limited number of centres (thus optimising knowledge in those centres and building true expertise) and the ability to develop a strong international reputation for a particular disease/disease area, to encourage professional collaborations.

She also outlined the work that is now being done through European Reference Networks (ERNs) and emphasized that as these Networks are built upon the premise of uniting disease-specific expert centres, it will be easier for countries outside of the EU/EEA to eventually engage (albeit informally) with these Networks where they have a clear vision of their existing expertise. This therefore reinforces the need for proper CE designation. Prof. Dr. Svetozar Damjanović, chair of the Republic Expert Committee on Rare Diseases at the Ministry of Health noted that EUCERD Recommendations

have been used as a starting point to specify the designation process of CEs in Serbia, with only some of them adapted to better suit the specifics of Serbia.

- **Expected outcomes in the near future, medium and long term, setting out in particular the expectations from the patients and their families:**

In order to emphasize the patient perspective, Mrs. Ivana Badnjarević, NORBS Vice President, gave a touching account of her family's experience with getting a proper diagnosis and treatment for her daughter. In her presentation, she outlined the experience in a couple of Serbian hospitals and compared it to the experience and care of one of the CEs abroad. The aim of her presentation was to show that PLWRD and their families expect a concrete set of steps to be taken in order for the best possible level of care in country, comparable to that of more developed EU countries. Attaining this level of care would be beneficial not only for PLWRD, but also for the treating physicians. The discussion after the presentations showed that most of the participants agree on a set of short term, mid term and long term goals - short term, the designation criteria for CEs need to be amended and put into practice; mid term, proper, adequate and sustainable funding for designated CEs needs to be established; long term, properly designated and financed CEs would be able to provide much better level of care for PLWRDs.

- **Which actions/ measures need to be taken:**

The concrete steps that need to be taken, and their respective timeframes are as follows:

- o Adoption of National Strategy for Rare Diseases of Serbia, by end of 2017
- o Continuation of the multistakeholder Task-Force which elaborated the NS, with a focus on overseeing the implementation and evaluation of the Strategy
- o Implementing the set of criteria for designating CEs for RDs outlined in the NS, by mid 2018
- o Designating first set of CEs for RDs by the end of June of 2018
- o Ensuring funding for designated CEs in 2018 and beyond

## **THEME 2 - IMPROVING ACCESS TO RARE DISEASE TREATMENTS**

- **Identification of specific gaps, challenges and needs:**

Even though some RD treatments were available through the state owned Health Insurance Fund's approved drugs' lists prior to 2012, most of very expensive orphan drugs were not reimbursed. This is why in 2012 Ministry of Health dedicated a part of its budget to treating RD patients with orphan drugs. This budget was around 1 million EUR in 2012, increasing incrementally to around 8,5 million EUR in 2017. The number of rare diseases reimbursed through this budget was, and still is, fairly limited - only Inborn Errors of Metabolism, some forms of Rare Cancers and HAE are being treated this way. Another notable point is that while the budget is being increased, and promises have been made for the 2018 budget to be increased yet again, this is being done *ad hoc* and not at all according to the needs. No proper assessment has been made of the needs, both inside the so-called "priority diseases" and outside. This assessment would be a hugely complex undertaking, made much simpler with the creation of the National Registry for RDs, which doesn't yet exist.

In 2015, faced with a similar situation, NORBS conducted a huge survey on the need for orphan drugs, and presented it to the public in October. The results of this survey showed that a RD budget of around 50 million EUR per year is necessary, in order for most of the patients to be reimbursed. Feeling that progress and comprehension of the needs by the institutions is still not satisfactory, NORBS decided to do another survey in 2017, this time concentrating not only on the needs for orphan drugs, but also launching a survey encompassing needs for supplements, medical devices and surgical procedures. The results of this survey have been presented as part of discussion on Theme 2 of the EUROPLAN workshop.

- **Assessment of the integration of European guidelines and policy recommendations into the national system:**

Since no European level policies exist obliging a country to provide a certain type of drug or a treatment to patients, leaving instead this type of decisions to national authorities, NORBS tried to provide a good practice example from Croatia, which is Serbia's neighbouring country, with similar laws and procedures. In order to provide the overview of the Croatian situation, NORBS invited Dr. Jelena Matuzović from the Croatian Health Insurance Fund, which presented the so-called "list of expensive medications", through which many expensive treatments, including orphan drugs are being reimbursed. The aim of this list is to dedicate a part of the budget for expensive drugs, therefore effectively separating it from the "regular drugs" budget. This makes planning more efficient, and helps put a special priority on patients that need expensive drugs.

Even though this example has been discussed numerous times in the past with the decision makers in Serbia, it is considered that a substantial effort is needed to implement something like this in Serbia, and it is not yet clear that the political will exist to make this huge and important step. As it stands, currently there are three different ways for patients to be reimbursed, and there is no certain set of rules to follow for patients in order to get the needed treatment.

- **Expected outcomes in the near future, medium and long term, setting out in particular the expectations from the patients and their families:**

Ministry of Health representative Dr. Dragana Vujičić outlined the need to provide more funding in the future, and also assured the participants that the Ministry is working on finding additional funding sources, while Serbian Health Insurance Fund representative Ms. Vesna Vuković mentioned all of the different ways in which the drugs in Serbia are being reimbursed. NORBS Executive Director, Mr. Davor Duboka then presented the NORBS survey results on access to treatment, drawing out conclusions from the data gathered:

- Close to 300 survey participants
- 70% answered they needed one/more drugs
- 23% answered they needed some form of supplements
- 36% need medical devices
- 16% need surgical procedures/transplantations

- **Which actions/ measures need to be taken:**

The presentation of survey results was followed by a discussion, through which some of the most important conclusions were drawn, as a set of global recommendations, and therefore without a timeframe:

- The need to have a singular method of reimbursing RD treatments (participants, especially external participants, felt the current situation was particularly complex)
- The need to allow reimbursement of supplements where/when needed
- The need to adapt the list of approved medical devices with the needs of PLWRD
- Additional funding needed: approximately 40 million EUR on top of current budget for orphan drugs; additional 10 million EUR for higher quality and/or unlisted types of medical devices
- The need to work on better access to transplantations (especially lung and heart)

### THEME 3 - SPECIALISED SOCIAL SERVICES FOR PLWRD

- **Identification of specific gaps, challenges and needs:**

The area in which the least progress was made in Serbia in relation to rare diseases in the past decade is social services and integration of PLWRD in existing social welfare practices. On one hand, there is a lack of understanding of the specific needs of PLWRD. On the other hand, relevant institutions are unwilling to recognise and adapt to disabilities outside the predefined "usual" sets, which makes it hard for PLWRD to exercise their rights to financial and other types of social welfare support. With many personnel changes at the Ministry of Social Welfare, it has been exceptionally hard to gain ground and start meaningful discussions. This is the reason why the need for specialised social services has been emphasized at the Conference.

- **Assessment of the integration of European guidelines and policy recommendations into the national system:**

Mrs. Dorica Dan, Board member of EURORDIS-Rare Diseases Europe, started the discussion by outlining the Recommendations to support the incorporation of Rare Diseases into Social Services and Policies, adopted by the European Commission Expert Group on Rare Diseases in 2016. She also presented the results of the INNOVCare/Rare Barometer survey "Juggling care and daily life - The balancing act of the rare disease community". These two presentations were then discussed as cornerstones when working on incorporating RDs in Social Services in Serbia.

Dr. Ljerka Cvitanović-Šojat, from the Croatian Institute for disability assessment presented an excellent example of disability assessment adapted to the needs and constraints of PLWRD, with the main purpose of looking further than physical disability, and incorporating sensory impairments in the assessments.

Unfortunately, Ministry of Social Welfare representatives were absent from this session, and it is expected that the talks with them are going to be continued at a later time.

- **Expected outcomes in the near future, medium and long term, setting out in particular the expectations from the patients and their families:**

It is far too early to talk about expected outcomes, as the communication with the institutions has been only intermittent at best. However, the expectations of PLWRD are high, as many of them are facing enormous obstacles in access to their social welfare rights. The outlined recommendations and best practice examples are, however, the most appropriate way forward.

- **Which actions/ measures need to be taken:**

The discussion after the presentations outlined a couple of steps that could be feasible in the current situation:

- Considering the amendments to disability assessment, bringing it in line with the needs of PLWRD
- Supporting the creation of Specialised Social Services which cater for the needs of PLWRD

### III. Conclusions

**Theme 1 - Centres of Expertise for Rare Diseases** produced a fruitful discussion through which it became obvious that there is a need for following the recommendations for the designation of CEs at the national level, all the while keeping in mind that these Centres need to be supported by proper funding.

**Theme 2 - Improving Access to Rare Disease Treatments** outlined a number of challenges, and put a spotlight first and foremost on proper distribution of the available funding, as well as the need to provide additional funding not only for orphan drugs, but also for supplements and medical devices. It also outlined the need for better access to transplantations for the patients that need them.

**Theme 3 - Specialised Social Services for PLWRD** set out recommendations to follow in further discussions with the institutions. Even though this is the area where the least progress was made, the participants agreed that most of the problems here stem from a system that is not adapted and is not recognising PLWRD, and much less from the need for a substantial financial investment.



**LIST OF PARTICIPANTS BY STAKEHOLDERS' CATEGORIES**

<b>NORBS - National organisation for Rare Diseases of Serbia</b>	<b>12</b>
<b>Ministry of Health, Ministry of Social Security and public institutions</b>	<b>13</b>
<b>Health care providers</b>	<b>18</b>
<b>Laboratories and pharma</b>	<b>25</b>
<b>Researchers</b>	<b>2</b>
<b>EURORDIS</b>	<b>2</b>
<b>Others</b>	<b>7</b>
<b>Total</b>	<b>79</b>

**Regional EUROPLAN conference**  
**"Rare Disease therapies - a road to solution"**  
Chamber of Commerce of Serbia, Resavska 13-15, Belgrade, Serbia  
*8 November 2017*

<b>PART 1 - Opening and welcome addresses</b>		
10:00 - 10:10	Welcome speech	<b>Dr. Zlatibor Lončar</b> , Minister of Health of Serbia
10:10 - 10:20	Welcome speech	<b>Dr. Verica Lazić</b> , Director General of National health insurance fund of Serbia
10:20 - 10:30	Welcome speech	<b>Sanda Savić</b> , President of the Board of Association for pharmaceutical and medical commerce, Chamber of Commerce of Serbia
10:30 - 10:40	Welcome speech	<b>Dorica Dan</b> , EURORDIS Board of Directors
10:40 - 10:50	Welcome speech	<b>Prof. Dr. Vojin Rakić</b> , head of the Help Us project
10:50 - 11:00	Welcome speech	<b>Davor Duboka</b> , NORBS Executive Director
11:00 - 11:30	Q&A, coffee break	
<b>PART 2 - Panel discussion on Centers of Expertise for Rare Diseases</b>		
11:30 - 11:40	Introduction to the panel discussion and the panelists	<b>Danijela Davidov Kesar</b> , panel moderator
11:40 - 12:00	EU Recommendations on Centers of Expertise and ERNs	<b>Victoria Hedley</b> , Newcastle University
12:00 - 12:20	Serbian National Strategy recommendations on Centers of Expertise	<b>Prof. Dr Svetozar Damjanović</b> , chair of working group on Serbian National Strategy
12:20 - 12:40	Center of Expertise for Rare Diseases - a personal perspective	<b>Ivana Badnjarević</b> , NORBS Vice President
12:40 - 13:30	Panel discussion: Centers of Expertise for Rare Diseases - implementing recommendations and fostering collaboration	<b>Victoria Hedley, Prof. Dr. Svetozar Damjanović, Ivana Badnjarević</b> , Ministry of Health representative
13:30 - 14:30	<b>LUNCH</b>	

<b>PART 3 - Funding of Rare Disease treatments</b>		
14:30 - 14:35	Introduction	Danijela Davidov Kesar, panel moderator
14:35 - 14:50	Orphan drugs: Ministry of Health activities and initiatives	<b>Dr. Dragana Vujičić</b> , Ministry of Health of Serbia
14:50 - 15:05	Status quo of orphan drugs in EU and Serbia - pricing, reimbursement, market access and funding survey results	<b>Davor Duboka</b> , NORBS Executive Director
15:05 - 15:20	National Health Insurance Fund role in reimbursing treatments to rare disease patients	<b>Vesna Vuković</b> , National Health Insurance Fund of Serbia
15:20 - 15:35	Expensive Drugs List at the Croatian Health Insurance Fund	<b>Dr. Jelena Matuzović</b> , Croatian Health Insurance Fund
15:35 - 16:10	Panel discussion: improving access to drugs for rare diseases in Serbia	<b>Dr. Dragana Vujičić</b> , Ministry of Health of Serbia, <b>Dr. Jelena Matuzović</b> , Croatian Health Insurance Fund, <b>Vesna Vuković</b> , National Health Insurance Fund of Serbia, <b>Davor Duboka</b> , NORBS
16:10 - 16:30	<b>Coffee break</b>	
<b>PART 4 - Specialised social services for Rare Diseases</b>		
16:30 - 16:45	Ministry of social welfare and its role in the National Strategy on Rare Diseases in Serbia	<b>Ministry of Social Welfare</b> representative
16:45 - 17:00	Specialised social services for people living with rare diseases - an European overview	<b>Dorica Dan</b> , EURORDIS
17:00 - 17:15	The Unique Expertise System for Children With Handicaps, Developmental Disabilities, Rare and Chronic Diseases in Croatia	<b>Prof. Dr Ljerka Cvitanović-Šojat</b> , D. Došen, D. Gavrić, B. Kosanović, S. Bilać, R. Dulić, S. Dominiković Šafranić, R. Nevistić, D. Bulić, Z. Jelaš, E. Martinac, Institute for Expert Evaluation, Professional Rehabilitation and Employment of People with Disabilities, Croatia
17:15 - 17:30	NoRo Center - a Balkans example of a specialised social service	<b>Dorica Dan</b> , EURORDIS
17:30 - 18:00	Q&A	