EUROPLAN
European Project for Rare Diseases National Plans Development
Coordinated by the Italian National Centre for Rare Diseases
Italian National Institute of Health
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NORBS
NACIONALNA ORGANIZACIJA ZA RETKE BOLESTI SRBIJE

EURORDIS
Rare Diseases Europe

SERBIA

EUROPLAN NATIONAL CONFERENCE

FINAL REPORT

6 – 7 December 2013, Belgrade

EUCERD
Joint Action

FOREWORD

The EUROPLAN National conferences are aimed at fostering the development of a comprehensive National Plan or Strategy 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 are jointly organised in each country by a National Alliance of rare disease patients' organisations and EURORDIS – the European Organisation for Rare Diseases. For this purpose, EURORDIS nominated 10 EURORDIS-EUROPLAN Advisors - all being from a National Alliance - specifically in charge of advising two to three National Alliances.

EUROPLAN National conferences share the same philosophy, objectives, format and content guidelines. They involve all stakeholders relevant for developing a plan/strategy for rare diseases. According to the national situation of each country and its most pressing needs, the content can be adjusted.

During the period 2008-2011, a first set of 15 EUROPLAN National Conferences were organised within the European project EUROPLAN. Following the success of these conferences, a second round of up to 24 EUROPLAN National Conferences is taking place in the broader context of the Joint Action of the European Committee of Experts on Rare Diseases (EUCERD) over the period March 2012 until August 2015.

The EUROPLAN National Conferences present the European rare disease policies as well as the EUCERD Recommendations adopted between 2010 and 2013. They are organised around common themes based on the Recommendation of the Council of the European Union on an action in the field of rare diseases:

1. Methodology and Governance of a National Plan;

2. Definition, codification and inventorying of RD; Information and Training;

3. Research on RD;

4. Care - Centres of Expertise / European Reference Networks/Cross Border Health Care;

5. Orphan Drugs;

6. Social Services for RD.

The themes "Patient Empowerment", "Gathering expertise at the European level" and "Sustainability" are transversal along the conference.

General information

Country	**Serbia**
Date & place of the National Conference	**06 and 07 December 2013**
Website	**www.norbs.rs**
Organisers	**National Organisation for Rare Diseases of Serbia (NORBS)** **and** **Institute for Molecular Genetics and Genetic Engineering of the Belgrade University (IMGGE)**
Members of the Steering Committee	**Prof. Dr. Dušan Milisavljević, MP** **Dr. Periša Simonović, Ministry of Health** **Dr. Dragan Delić, Health Council of Serbia** **Prof. Dr. Svetozar Damjanovic, president of the Committee for Rare Diseases of the Ministry of Health** **Dr. Svetlana Popadić, Clinical Center of Serbia** **Vlasta Zmazek, EURORDIS** **Dr Maja Stojiljković Petrović, Institute for Molecular Genetics and Genetic Engineering** **Jelena Milošević, NORBS president** **Dragana Koruga, NORBS vice president** **Marija Joldić, NORBS** **Sadra Pavlović, NORBS** **Davor Duboka, NORBS executive director**
Names and list of Workshops	**W1 - The infrastructure and methodology necessary to develop and implement the National Plan for rare diseases - experiences from Croatia, perspective in Serbia** **W2 - Patient Empowerment - Experiences from Serbia and the region** **W3 - Standards of care of RD patients and**

	Centres of Expertise **W4 - Definition, Codification and Inventorying of Rare Diseases** **W5 - Scientific research on Rare Diseases** **W6 - Patients' rights within the healthcare and social welfare policy in Serbia**
Workshop Chairs (and Rapporteurs, where applicable)	**W1 Davor Duboka** **W2 Jelena Milošević** **W3 Mirjana Grujić Brojčin** **W4 Dragana Koruga** **W5 Marija Joldić** **W6 Jelena Milošević** **Rapporteurs: Jelena Milošević, Dragana Koruga, Marija Joldić and Mirjana Grujić Brojčin**
Annexes:	**I. Programme** **II. List of Institutions** **III. List of Participants**

Main Report

Plenary Report – Opening Session

Conference Opening

The First National Conference on rare disease was opened on 6 December 2013 at the hotel Holiday Inn in Belgrade. Opening speeches were delivered by Dr. Periša Simonović, State Secretary of the Ministry of Health of the Republic of Serbia, Prof. Dr. Dušan Milisavljević, Member of Parliament, Chairperson of the Serbian National Assembly's Health and Family Committee, as well as by Dr. Jelena Begović, director of the Institute for Molecular Genetics and Genetic Engineering which was the co-organizer of this Conference and Jelena Milošević, President of the National Organization for Rare Disease of Serbia.

Plenary Session

At the plenary session, Yann Le Cam presented EURORDIS and EU documents regulating the field of rare diseases, paying special attention to the importance of creating the National Plans as comprehensive documents at the national level intended for the regulation of the field of rare diseases. Next, Vlasta Zmazek, EURORDIS EUROPLAN Advisor, presented the EUROPLAN project.

Prof. Dr. Svetozar Damjanović, Chairperson of the Republic Expert Committee for Rare Diseases established by the Ministry of Health, commented on the status of rare diseases in Serbia, speaking on how the solving of the legal status of persons with rare diseases began, using the example of orphan drugs. Then he spoke of the fact that, at the moment, there was no possibility of keeping precise record on the diseases, hence it was also impossible to collect precise epidemiological data. After this introduction, he presented the proposal of the **Strategy for Rare Diseases** written by the members of the Republic Expert Committee. The primary task identified by the Republic Expert Committee in the Strategy is designating the healthcare institutions which would become the centres for specific groups of rare diseases. Besides this primary task, the main tasks of the Strategy for the period by 2020 would be: improving diagnostics and treatment, improving availability of orphan drugs, registering of rare diseases, screening for rare disease, increasing the participation of patients' association, creating a scientific-research programme dealing with the studying of rare diseases. Also, prof. Damjanović stressed the need for the inclusion into defined streams of European policies, as well as the need for the establishing of university centres of expertise in the way defined by the Strategy proposal.

Dr. Periša Simonović, State Secretary of the Ministry of Health, speaking about the legal framework created in the health care area with regard to the rare diseases, specified the lack of coordination between the different parts of public administration as the largest problem in the field of rare diseases. Vladimir Pešić from the Ministry of Labour, Employment and Social Policy spoke about the reforms in the area of social welfare, and about the new rules enabling better quality of life to the beneficiaries of social-welfare entitlements. Dr. Snežana Plavšić from the National Institute of Public Health "Batut" reiterated that there were no precise

epidemiological and statistical data in Serbia, and added that the data from health care institutions did not provide a clear enough picture. Therefore an idea occurred on the establishing of a centralized database, which would contain the data on individual rare diseases and groups of rare diseases. Dr. Zoran Vlahović from the Republic Health Insurance Fund said that the Republic Fund would support through its activities all decisions and laws to be adopted in the field of rare diseases.
The Conference was organized by NORBS - National Organization for Rare Diseases of Serbia, with the Institute for Molecular Genetics and Genetic Engineering of Belgrade University as co-organizer, and under the auspices of the Ministry of Health of the Republic of Serbia and EURORDIS - European Organisation for Rare Diseases. The huge success of this two-day Conference was that, for the first time, the representatives of all stakeholders gathered at the same place: representatives of legislators, Ministries in charge of health and social welfare, Health Insurance Fund, healthcare professionals, patients' associations, pharmaceutical industry, and the students of the Medical Faculty who volunteered to assist at the Conference - in total more than 170 participants.

Apart from domestic participants, the Conference was also attended by the foreign experts and representatives of associations from Slovenia, Croatia, Bosnia and Herzegovina, Montenegro and Austria.

Report of Workshops

Theme 1 - Methodology, Governance and Monitoring of the National Plan

Sub-Themes:

1.1 Mapping policies and resources

1.2 Development of a National Plan /Strategy

1.3 Structure of a National Plan /Strategy

1.4 Governance of a National Plan

1.5 Dissemination and communication on the National Plan

1.6 Monitoring and evaluation of the National Plan

1.7 Sustainability of the National Plan

Workshop 1
Chair: Davor Duboka, NORBS
Rapporteur: Sandra Pavlović, NORBS
Time and place: 6 December 2013, 14:30-16:00, Halls Studenica+Ravanica+Gračanica, Holiday Inn hotel
Number of participants: 80

Mapping policies and resources

Currently, in Serbia there are neither epidemiological data on rare diseases, nor a rare diseases registry. There are clinical registries for some rare diseases, or groups of rare diseases, but they depend on the personal initiative of some physicians.

Patients' association mostly rally around the umbrella organization – the National Organization for Rare Disease of Serbia, which unites representatives of 13 associations of persons affected by either individual rare disease or groups of rare diseases.

The legislative framework for rare diseases is very general, and it encompasses the obligation to provide treatment with enzyme substitution therapies for patients with inborn metabolic disorders, as well as the obligation to define centres for specific types of rare diseases, although this obligation has not been regulated yet through by-laws, only mentioned in the Law on Health Care.

The conclusion of the workshop with regards to this issue is that the talks between the Ministry of Health, the Republic Expert Committee for Rare Diseases and patients' associations should begin as soon as possible in order to create a true picture of the situation in the area of rare disease.

Development of a National Plan / Strategy

In early in 2013, the Republic Expert Committee for Rare Diseases prepared a proposal for a National Strategy for Rare Diseases, defining priority activity areas. However, until this moment that Strategy has neither been made available to the public, nor has the Ministry of Health come out with its standpoint regarding the proposal of the Republic Expert Committee.

The recommendation of this workshop is that the next step should be making the Strategy proposal available to the public and initiating constructive public discussions. Next, a task force should be established to define activities, objectives and time lines for the implementation of key areas from the National Strategy. Apart from the members of the Republic Expert Committee for Rare Diseases, members of this task force should also be the representatives of the National Organization for Rare Disease of Serbia, Ministry of Labour, Employment and Social Policy, Republic Health Insurance Fund. After the finalization and adopting of the Strategy, the task force should also manage its implementation. The conclusion is that the transparency of the process of the Strategy making could be ensured to a large extent through public discussions and inclusion of the representatives of all stakeholders.

Structure of a National Plan / Strategy

The discussion after the presentations focused on the three crucial issues of the National Strategy: diagnostics, laboratories and reference centres. The National Strategy recommends that reference centres should be formed within the already existing institutions so that the existing resources would be fully utilised. It has been stated that the Republic Expert Committee for Rare Diseases has already determined that five reference centres for rare diseases should be formed. Likewise, the list of the laboratories in the country has been made as well as the list of analyses those laboratories can provide. At the moment, there are no clearly defined goals and timelines defining the pace and activities in which the priority areas of the Strategy would be implemented.

Governance of a National Plan / Strategy

Since the National Strategy is still a proposal, the only conclusion related to the governance of the National Strategy is that a task force including the representatives of all stakeholders should be formed to finalize the Strategy, and afterwards govern, monitor and assess the Strategy implementation.

Dissemination and Communication on the National Plan

The discussion on the activities directed towards raising awareness, using the examples of diagnostics and laboratories, came up with a proposal on the establishing of an online portal with all relevant information on the topics regarding rare diseases: diagnostics, physicians and patients' associations. The proposals regarding the setting up of such portal concerned using the infrastructure already existing within Orphanet Serbia, or, alternatively, that the portal should be established at the level of the Ministry of Health or Republic Health Insurance Fund, which would require additional financial and human resources.

Conclusions

The participants agreed that this workshop raised a series of questions to be discussed at all levels over the forthcoming period, but also that the state's commitment towards all the aspects of the making and implementing of the National Strategy has to be a priority. Only then it will be possible to make the next concrete steps and they would be:

1. establishing of the task force to work on the National Strategy development;
2. determining objectives and time lines for the National Strategy implementation;
3. providing special financial resources aimed at making and implementing the National Strategy and at the monitoring of all its aspects.

Theme 2 - Definition, codification and inventorying of RD

Sub-Themes:

2.1 Definition of RD

2.2 Codification of RD and traceability in national health system

2.3 Registries and databases

2.4 Information on available care for RDs in general, for different audiences

2.5 Help Lines

2.6 Training healthcare professionals to recognise and code RD

2.7. Training healthcare professionals

Workshop 4
Chair: Dragana Koruga (NORBS)
Rapporteur: Marija Joldić (NORBS)
Time and place: 6 December 2013, 16:30-18:30, Halls Ostrog+Žiča+Mileševa, Holiday Inn hotel
Number of participants: 45

Definition of RD

Although there is no official definition of a rare disease in Serbia, the generally accepted and used definition is EU's official definition – a rare disease is the disease affecting no more than 5 in 10,000 persons.

Codification of RD and traceability in national health system

The International Classification of Diseases (ICD-10) is used in Serbia. This codification system allows for the health insurance users to exercise certain rights on the grounds of the code of their disease. Rare diseases in Serbia are not particularly codified in any way.

Registries and databases

In Serbia there are no national registries, neither of individual rare diseases nor of groups of rare diseases.

Also, Serbia does not have the common or comprehensive national registry of rare diseases. The current situation is as follows: there are hospital/clinical databases in certain clinical centres that have a history of treating certain rare diseases. These databases are not always mutually compatible. Apart from not being compatible, they are available only to a small circle of physicians specialising in these diseases. For the most part there are no integrated databases in Serbia, collecting the data from more than one clinical centre. Every database, even within one group of rare diseases, has been made in accordance with the priorities of a specific physician or particular clinical centre/hospital.

Information on available care for RDs in general, for different audiences

Only patients' associations and NORBS as the national association of individual associations and individuals with RDs inform the public on the availability of treatment of specific RDs. National health care institutions and services do not have a developed system for informing patients on rare diseases, on their rights, pathways of establishing a diagnosis in the country and abroad and on patients' rights in that domain, nor on the available therapeutic methods in the country, both the ones covered by the Serbian health insurance and those that are not covered by insurance. One may say that the public and patients with rare diseases are poorly informed, that they often do not know they are suffering from a rare disease and they do not know whom to consult with regard to their condition.

The portal ORPHANET Serbia has been established and it provides an abundance of information. Unfortunately, this portal is insufficiently used both by the patients/potential patients and by the professionals. There are many reasons for this: from insufficient availability of the Internet and modern technologies, to the lack of knowledge of a foreign language and

insufficient education necessary in order to understand the offered information (however basic they might be).

Help Lines
Serbia neither has free-of-charge telephone lines to provide information, support and assistance to the persons with rare diseases, nor is their setting up within official institutions and healthcare system facilities planned at the present time.

Training healthcare professionals to recognise and code RD
As rare diseases are not codified in Serbia, it has been concluded that training will be possible only after the adoption of the codifying system and the National Plan for rare diseases which will include a training plan.

Training healthcare professionals
In Serbia, training of physicians, especially paediatricians, takes place regularly within the national system of professional development, as well as at international meetings and conferences. However, it has been concluded that the level of information and education of physicians with regard to rare diseases is still very low. On the other hand, it has been observed that the physicians distinctly show interest to learn more about rare diseases and that their needs in this respect are not sufficiently met. It has also been noticed, that, on the other hand, the resources available in neighbouring countries are underutilised, primarily the knowledge and expertise of RD experts from these countries (especially of those from the countries speaking similar languages).

Conclusions
The workshop participants agreed that, in order to enable codifying and registering of rare diseases, the National Plan for rare diseases should envisage the following:

1. Procedures and mechanisms for establishing a unified system of codification of rare diseases in Serbia so that the data from the registries/databases can be easily linked and flow into an integral central registry/base.
2. Provide that the system of codification of individual rare diseases be recognized in the healthcare and social welfare systems (for the exercising of all the rights a patient is entitled to)
3. Ensure broad public support for the adoption and implementation of the National Plan on rare diseases (from the media, politicians, public institutions, rare diseases experts, scientific and research circles, corporate sector)

For a central registry of rare diseases to function, after it has been established, the following needs to be done:

1. Precisely determine steps and procedure for the establishing of a central registry of rare diseases and registries/databases of individual rare diseases within reference centres, define five year plan for implementation of rare diseases codification system, timelines and responsibilities;
2. Define legal regulations and mechanisms to ensure flow of validated data from

databases/registries kept at reference centres into the central registry, for example integrated information system within Serbian healthcare system and integrated system of keeping records and documentation on rare diseases;

3. Ensure compatibility of data in the national registry of rare diseases with the rare diseases registries at EU level (primarily in order to ensure the availability of clinical studies and other research for the benefit of patients, diagnostics, experts, treatment and medications);
4. As soon as possible, commence creating a form for the collecting of data on rare diseases and entering those data into a database kept at the Serbian Institute of Public Health which was designated by the Republic government to execute this task. Therefore, a team or a person should be appointed to execute this task and the work performed should be financed through projects supported by IPA (Instrument for Pre-Accession Assistance) or similar funds or could be performed through voluntary work (physicians, medical students or postgraduate students).

One of the conclusions is that although the Serbian ORPHANET portal has been established and functioning, the general impression is that the portal is not used to a satisfying extent. With regard to that issue the following should be done:

1. Provide better exchange of information among experts, scientists and projects through ORPHANET Serbia by organizing public events for learning and exchanges;
2. Increase the visibility and availability of information on RDs to the public;
3. Increase the interactivity of the web site of the National Organization for Rare Diseases in order to facilitate the exchange of information and experiences; also, links towards the ORPHANET Serbian portal and web sites of individual associations-members of NORBS should be placed on NORBS' website;
4. Encourage and assist the member associations to increase, as much as possible, the level of available information on a concrete RD or group of diseases, especially for those groups for whom electronic information is less available or which have other sorts of constraints when searching for the information.

With regard to the help lines for rare diseases, this workshop recommends considering the possibility for the National Organization for Rare Diseases to establish an SOS line, i.e. the support line for RDs, which would serve for better information, prompt and efficient obtaining of information on the rights of patients suffering from a specific rare disease, diagnostic and treatment possibilities and other current information.

When it comes to health care professionals training on rare diseases, the workshop conclusion is that there is a need for the provision and enabling of better and more intensive mutual linking and networking of interest groups in the country and abroad, at all levels.

Theme 3 - Research on RD

Sub-Themes:

3.1 Mapping of existing research resources, infrastructures and programmes for RDs

3.2 Dedicated RD research programmes and governance of RD research funds

3.3 Sustainability of research programmes on RD

3.4 Needs and priorities for research in the field of RDs

3.5 Fostering interest and participation of national laboratories and researchers, patients and patient organisations in RD research projects

3.6 RD research infrastructures and registries

3.7 EU and international collaboration on research on RD

Workshop 5
Chair: Marija Joldić (NORBS)
Rapporteur: Sandra Pavlović (NORBS)
Time and place: 7 December 2013, 9:00-11:00, Halls Studenica+Ravanica+Gračanica, Holiday Inn hotel
Number of participants: 60

Mapping of existing research resources, infrastructures and programmes for RDs
The research resources and infrastructures for RDs in various disciplines cannot be estimated due to the fact that a conjoined list of all researches on RDs conducted in laboratories or clinics does not exist.
At this point, there are no researches initiated by patients in Serbia.
There is no public-official list or record of the teams working on rare disease research at the national level. However, every clinic or laboratory engaged in rare diseases research has its own list of researchers working on that project.

A special research programme for RDs with purpose-specific funds at national level does not exist. Everything is financed from the common budget for all research projects. There is an ongoing project on molecular diagnostics of rare diseases. This is a National project III 41004: Rare Diseases, comprising 8 sub-projects with 80 researchers currently working on them. However, it is not financed from a special programme - rather from the budget of the Ministry.

Dedicated RD research programmes and governance of RD research funds
There is no dedicated research programmes specifically aimed at RDs.

Sustainability of research programmes on RD
Due to the fact that specific-purpose RD research programmes do not exist, the sustainability of these programmes cannot be discussed.

Needs and priorities for research in the field of RDs

A research on the needs and priorities for fundamental, clinical and translational research has not been conducted in our country.

The awareness of the need to research the quality of life, living conditions and perform social research on rare diseases can be improved by the empowerment of the role of the National Organisation for Rare Diseases of Serbia, as an umbrella organisation which should gather as many associations dealing with individual RDs as well as individuals, persons with RDs through the entire society. The active participation and presence of NORBS in the commissions and working bodies of the Ministry of Health, Ministry of Labour, Employment and Social Policy, Health and Family Committee of the Serbian National Assembly (The Parliament), media and web channels, can help raise awareness of RDs, speak out on the problems people who live with RDs face and the needs of research on the quality of life of this group.

Fostering interest and participation of national laboratories and researchers, patients and patient organisations in RD research projects

The active participation and collaboration of researchers and patient associations in RD research projects is necessary.

Since the Serbian National Plan/Strategy is still in a proposal stage, we can only discuss the recommendation stated in the proposal that reference centres should be established within the existing institutions in order to fully utilise the existing resources. The proposal envisages the establishing of five reference centres for RDs. Only after the establishment of these reference centres, the measures for fostering multi-focal research activitiescan be discussed.

Connections between researchers and patients can be strengthened by encouraging the registration of experts, laboratories, clinics and patient organisations at the Orpha.net Serbia Portal. It is also necessary to encourage patient associations to connect with other associations in the world via Rare Connect.

RD research infrastructures and registries

There is no RD registry in Serbia. The development of RD registries will begin after the adoption of the Law on Public Data and Records in the Health Care System of Serbia which is foreseen to be adopted.

EU and international collaboration on research on RD

The project financed by the European Union: RegPot SERBORDISinn (Strengthening the Research Potential of IMGGE through Reinforcement of Biomedical Science of Rare Diseases in Serbia-en route for innovation) is ongoing. The subject of this project is predictive genetics: the platforms for the detection of mutations causing rare diseases and the complete genome sequencing.

Conclusions

A specific law regulating research in the domain of rare diseases does not exist. During the entire workshop, diagnostic has been stressed as a problem in our country. Despite the fact that Serbia is a poor country and not yet a member of the European Union, there is a network of laboratories. However, everything comes down to good will and personal initiative of

individuals. The proposed solutions are the establishment of a National laboratory located within a clinical centre which would enable the rare diseases analyses to be done at one centralized place, as well as educating young experts abroad.

Theme 4 – Care for RDs - Centres of Expertise and European Reference Networks for Rare Diseases

Sub-Themes:

4.1 Designation and evaluation of CE

4.2 Scope and functioning of CEs

4.3 Multidisciplinarity, healthcare pathways & continuity of care

4.4 Access to information

4.5 Research in CEs – How to integrate research on RDs and provision of care

4.6 Good practice guidelines

4.7 Diagnostic and genetic testing

4.8 Screening policies

4.9 European and international collaboration – Cross-border healthcare and ERNs (European Reference Networks)

4.10 Sustainability of CEs

Workshop 3
Chair: Mira Grujić Brojčin (NORBS)
Rapporteur: Irina Čepinac Ban (NORBS)
Time and place: 6 December 2013, 16:30-18:30, Halls Studenica+Ravanica+Gračanica, Holiday Inn hotel
Number of participants: 60

Designation and evaluation of CE

The workshop participants observed that there are no defined centres of expertise in Serbia, but that their establishing is of utmost importance. In addition to this, there is a plan for some clinics which already deal with certain group of rare diseases within the clinical centres to become centres of expertise for that group of rare diseases. At this point, there are clinics functioning de facto as the centres of expertise in Serbia. However, since they are not legally regulated as CEs, they are entirely dependent on personal initiative of certain healthcare professionals who organize their own work so as to achieve the greatest possible quality of care for their patients.

Scope and functioning of CEs

The workshop participants observed that the method for designating the centres of expertise is not defined by legislation. As a result, it is not possible to analyze the scope and functioning of CEs at this point. It has been suggested to follow the examples from the neighbouring countries represented at the workshop, as examples of good practice.

Multidisciplinarity, healthcare pathways & continuity of care

Multidisciplinarity in the clinical practice in Serbia is very poorly developed. The workshop participants agreed that it was necessary to strive to such treatment approach, stating as an example of good practice a possibility for physicians of other specialities to be consulted and engaged by the team within such multidiciplinary centres without sending a patient to another institution for further analyses – the team within the centre consults and invites physicians of other specialities. This method of work is based on the "patient-centered care" principle - the number of doctors of a multidisciplinary team is reduced to a minimum and the work related to individual patients is managed by a case manager. Due to the fact that this level of healthcare is practically higher than the tertiary one, the participants also stressed the problem of funding this multidisciplinary approach. Connecting the centres of expertise of small countries via regional centres is desirable precisely because of the difficulties related to the funding and functioning of the centres of expertise.

Access to information

It has been observed that in Serbia, except in individual cases, the centres where persons with rare diseases are treated do not have a practice of distributing the information that could be of use to the patients. As the examples of good practice, it was mentioned that certain clinics have well defined and developed cooperation with the representatives of patient associations, and that this is a two-way cooperation – the organizations receive information about newly-diagnosed cases, provide help, support and education both to patients and physicians.

Research in CEs – How to integrate research on RDs and provision of care

The participants agreed that Centres of Expertise could contribute greatly to the research activities in the domain of rare diseases they would be engaged in. In conclusion, it is necessary to strive to the establishing of CEs in the manner proposed by the EUCERD recommendations. It was also concluded that Centres of Expertise could facilitate data collection i.e. managing of the registries on rare diseases or groups of rare diseases they deal with.

Diagnostic and genetic testing

In Serbia, medical laboratories get accreditation from the Accreditation Body of Serbia, on the basis of the laboratory functioning in compliance with ISO/IEC17025 and ISO15189 standards. However, due to the high costs of accreditation, most laboratories in the country providing diagnostic services for rare diseases have not been accredited. Regardless of a laboratory having an accreditation or not, the creation of a list of medical laboratories providing

diagnostic services for rare diseases is underway with the aim to provide the diagnostics for rare diseases in the country at the expense of the Republic Health Insurance Fund based on that list. The protocols on cooperation with the laboratories abroad should be signed for the analyses which cannot be performed in Serbia. As far as diagnostics abroad is concerned, workshop participants jointly concluded that many administrative problems exist, such as slow and long-lasting process of obtaining permits for the transport of biological samples abroad etc. It was also mentioned several times that financing of diagnostics at the expense of the State both in the country and abroad has not been regulated yet, and that the diagnostic laboratories are not sufficiently linked, apart from certain exceptions.

As far as genetic counselling is concerned, the participants reached a conclusion that it is mostly performed further to a personal initiative, and that it varies from institution to institution. Additionally, there are no measures making the visit to genetic counselling centres compulsory, if there is a need for this. Likewise, low awareness as a consequence of the insufficient level of information is also an issue.

Screening policies

In Serbia the compulsory neonatal screening comprises the analyses for two rare diseases: phenylketonuria and congenital hypothyroidism. It has been concluded in the workshop that the increase of the number of diseases for which screening is performed would result in the improvement of the quality of life of those patients whose diseases demand for the treatment to start as soon as possible (i.e. Wilson's disease) in order to prevent severe consequences caused by the disease if not treated in time.

Sustainability of CEs

In order to provide the long-term sustainability of centres of expertise, within the National Plan for Rare Diseases it is necessary to earmark a part of the budget intended for the implementation of the Plan for the purpose of financing CEs.

Conclusions

Even though it has been concluded that the legal grounds to designate the centres of expertise do not exist, there is a positive example of domestic institutions that can be a promising inception of future centres of expertise. There is a possibility to better organize and network institutions and connect experts, with the aim to provide better quality and continuous care in various life ages.

The goal of such an approach is for patients, experts and expertise to be in one place which would result in an individual approach to a patient, all in compliance with the recommendations of the European Commission that an expert should travel rather than a patient.

The problem of provision of funding was stressed as a common issue for all diseases and all health care systems. The necessity to create national registries, as the foundation for the systematic management of rare diseases, which would be much easier if information could be

found in one, common place, was reiterated many times. In addition to this, the lack of systematic solution for the funding of rare disease diagnostics, in the country and abroad, as well as slow and complicated procedure for the sending of biological samples abroad, additionally complicate the treatment of rare diseases.

Theme 5 – Orphan Medicinal Products

Sub-Themes:

5.1 Support to Orphan Drug (OD) development

5.2. Access to treatments

5.3. Compassionate use programmes

5.4. Off label use of medicinal products

5.5. Pharmacovigilance

Theme 6 –Social Services for Rare Diseases

Sub-Themes

6.1. Social resources for people with disabilities

6.2. Specialised social services for rare diseases

6.3. Policies to integrate people living with rare diseases into daily life

Workshop: 6
Chair: Jelena Milošević
Rapporteur: Dragana Koruga
Time and place: 6 December 2013, 14:30-16:00, Halls Ostrog+Žiča+Mileševa, Holiday Inn hotel
Number of participants: 50

Sub-Themes:
5.1. **Support to Orphan Drug (OD) development**
5.2. **Access to treatments**
5.3. **Compassionate use programmes and off label use of medicinal products**
6.1. **Social resources for people with disabilities**
6.2. **Specialised social services for rare diseases**
6.3. **Policies to integrate people living with rare diseases into daily life**

Support to Orphan Drug (OD) development
The support to the development of orphan drugs neither exists nor is planned in Serbia. Only isolated cases of the initiation of clinical studies for these type of medications exist but without clearly defined legislation.

Access to treatments

The elementary obstacle recognisedat the workshop as the key one for the introduction and use of new orphan drugs in Serbia is the lack of funds. The participants stated that 130 million Dinars (some 1.2 million Euros) was allocated from the budget for this purpose in 2013, and that 280 million Dinars (some 2.6 million Euros) were planned to be allocated for this purpose in 2014. However, this sum covers the treatment with orphan drugs for only a small number of persons with rare diseases - only 10 juvenile patients were treated in Serbia in 2013. It was also concluded that all decisions on the necessity to be treated with orphan drugs were made by physicians – the members of the Republic Expert Commission for Rare Diseases of the Ministry of Health of the Republic of Serbia.

Compassionate use programmes and off label use of medicinal products

In Serbia, the only way for a patient to obtain a medical product is to have his diagnosis code to be included in the list of diagnoses for which the necessary product is prescribed. The compassionate use or off label use are not recognized in the health insurance system by any means. In order for both of these options for prescribing medical products to be introduced, it is necessary to allow them by amending legislation, namely the rule books of the Republic Health Insurance Fund and, if necessary, by amending the Law on Health Insurance.

Social resources for people with disabilities

Over the last decade, a series of laws were adopted in Serbia with the aim to provide support services, anti-discrimination and equality for persons with disabilities. These laws include: Law on Social Welfare, Law on Professional Rehabilitation and Employment, Law on Prevention of Discrimination against Persons with Disabilities, Law on the Ratification of the UN Convention on the Rights of Persons with Disabilities, Law on Social Housing, Law on Spatial Planning and Construction, Lottery Law, Law on Health Care, Law on Pension and Disability Insurance, etc. Even though these are high-quality laws, the problem is the fact that numerous provisions are not implemented in practice. Although the status of persons with disabilities is recognized in numerous positive laws, there is the lack of mechanisms for the application of laws (for instance, of the Law on Social Welfare) even when a person has a disability status on the basis of a rare disease. It is necessary to connect the healthcare and social welfare systems by recognizing rare diseases in the regulations defining the categories of beneficiaries entitled to certain benefits and elementary rights in the social welfare system (various aids, forms of nutrition, spa rehabilitation, accompanying physical and other therapy, etc.).

Specialised social services for rare diseases

In Serbia, specialised social services intended specifically for the persons with rare diseases do not exist. Persons with rare diseases are recognized by the social welfare system only if they are the beneficiaries of financial assistance, and not as persons suffering from rare diseases. It is necessary to connect the status of patients with rare diseases and the status of financial assistance beneficiaries. Still, due to the fact that the Law on Social Welfare recognizes the so-called "social health care services" for which the supporting regulations are yet to be adopted, it is necessary to pass these regulations and influence the social welfare system by including

the representatives of the National Organisation for Rare Diseases in these processes. Another existing problem is the lack of connection between medicines, aids and services and the rare disease diagnoses within the Republic Health Insurance Fund. The adjustment of all regulations dealing with the exercising of rights in the domain of social welfare for the persons with rare diseases has been stated as one of the solutions. In this domain too, the inclusion of NORBS in the bodies and processes dealing with these issues has been recognized to be of outmost importance.

Policies to integrate people living with rare diseases into daily life

In Serbia there are no clearly defined regulations on the integration of people with rare diseases into daily life. These rights are exercised through other regulations, mostly through the ones related to persons with disabilities; in this process the persons with rare diseases face numerous difficulties in the exercising of their rights. The persons with rare diseases who do not have the status of a disabled person cannot exercise the right in the domain of social welfare according to the current regulations. This proves that discrimination on various grounds still exists even though it is strictly prohibited by law. The conclusion of this workshop is that it is necessary to amend the existing Law on Social Welfare and accompanying by-laws, with the active participation of the representatives of the associations of persons with rare diseases in these processes.

Conclusions:

One of the major conclusions of this workshop is that to a great extent there is no connection between the healthcare and social welfare systems and services they provide to persons with rare diseases. In that regard, it has been concluded that is necessary to introduce a mechanism enabling the application of the solutions already existing in the current legislation, and that the individuals with disabilities need to be better informed and more involved in the work of their associations.

It has also been stated that there is an incompatibility between the Republic Health Insurance Fund's regulations and the needs of persons with rare diseases, in terms of the lack of connection between rare diseases diagnoses and medicines, medical devices and aids provided at the expense of mandatory health insurance. This, as well as many other problems related to the implementation of the laws regulating the domain of social welfare and health care, create a dilemma for persons with rare diseases and additionally complicate their already complex situation.

It has also been concluded that due to the above-mentioned non-recognition of the persons with rare diseases by the laws and regulations on social welfare, their conditions also remain unrecognized, causing for the persons with rare diseases to be discriminated in comparison with other persons who are the beneficiaries of the social welfare services.

Additional Workshop on Patient Empowerment

Workshop 2
Moderators: Jelena Milošević (NORBS), Vlasta Zmazek (EURORDIS), Mira Grujić Brojčin (NORBS), Vesna Aleksovska ("Life with Challenges", Macedonia)
Rapporteur: Jelena Milošević (NORBS)
Time and place: 6 December 2013, 14:30-16:00, Halls Ostrog+Žiča+Mileševa, Holiday Inn hotel
Number of participants: 45

Introductory remarks:
The workshop addressed the issues of living with a rare disease, not losing hope, preserving enthusiasm and courage in one's life. The moderators shared their personal and professional experience related to rare diseases and then started the discussion about the fact that all of them had different diseases but faced the same or similar problems and difficulties.
Vlasta Zmazek presented her personal experience of a mother of an already grown-up child with a rare disease from the very beginning, and spoke about the setting up of "Debra" in Croatia. She emphasized the importance of physicians being educated by patients and their parents, of patients networking, of continuous pressure on competent persons and institutions and of active participation in working groups for the creation/amendment of laws and regulations.
Vesna Aleksovska spoke about her experience of a patient who had no hope and who lived with her disease for 21 years since she had been diagnosed, as well as about the treatment that had changed her life. Nowadays, she has been running an organization for rare diseases for already five years, trying to change the situation related to rare diseases and the treatment of patients and their families in Macedonia. She stressed that patients are the most important link in the process of improving the quality of their lives and they must not give in.
Mirjana Grujić Brojčin spoke about her experience of a mother of an underage child with Epidermolysis Bullosa, everyday problems and challenges resulting from this rare disease as well as about the work of the organization "Debra" in Serbia.
Jelena Milosevic spoke about the philosophy of independent living of persons with disabilities which can also apply to the life of persons with rare diseases. Still, in order for this philosophy to be put into practice, it is necessary to fulfill certain pre-conditions (having personal assistance, removal of architectural barriers, availability of assistive technology). In general, persons with disabilities and rare diseases have the same needs and should have the same rights as anybody else.

Conclusions:
All participants were extremely active, sharing their opinion on what it is like to be a patient, a member of a patient's family or a health care professional. Everybody agreed that cherishing hope, courage, enthusiasm and motivation is the most important for the improvement of the quality of life of persons living with rare diseases and that this can be achieved primarily by:
- uniting and networking persons with rare diseases and members of their families;
- organizing various activities aimed at raising awareness and educating both persons with rare

diseases and their familiesas well as the physicians;
- cooperation between professional organizations, competent institutions and associations of persons with rare diseases;
- cooperation with international organizations in order to exchange experience and information.

The participants also exchanged experience on difficulties and problems they had encountered and the manners in which they had coped with them. After the workshop, the participants were asked to write down several sentences on how they saw life with a rare disease. Some of the sentences were: "I love to play, I love to walk, I love to be happy, I love to love – therefore, do not take away my freedom and my right to live.", "Teamwork is important, one should not fight on his own", "Little people are big too", "Hope is what keeps me going", "We are all the same, we are all equal, we should never speak or act against each other", "I don't want to hide my illness, this is who I am", "Humans, animals and plants – the world, we are all together".

Report of the Closing Session - Conclusions

- **Overall assessment of the usefulness of the European guidelines and policy recommendations**
- **Identification of specific gaps, challenges and needs across all Themes.**

The first national conference on rare diseases in Serbia, for the first time, assembled the most relevant representatives of various interest groups in the area of rare diseases, thus enabling the exchange of information, and more than anything else, making the decision makers familiar with the European recommendations in the area of rare diseases. Insisting on the systematic solving of issues concerning persons with rare diseases was additionally encouraged through the presentation of EUROPLAN and EUCERD's Recommendations at the Conference Plenary Session, which were later on discussed by participants in all of the workshops.

It has been concluded that these Recommendations are exceptionally important as they represent a good framework covering all relevant aspects of problems associated with rare diseases, but, also, that a part of those Recommendations cannot be implemented in our country in the forthcoming period (e.g. participation in the European Reference Networks at the moment when centres of excellence in our country are yet to be designated) or that they are inapplicable due to certain constraints encountered by countries with small number of inhabitants.

The topics covered within Conference programme provided an opportunity to look into the current situation in this area, as well as into the future planned steps, and also into the steps that should be undertaken, but which had not been planned by the competent institutions. The problems and the needs that were mentioned and discussed most in individual workshops were rather clearly grouped:

1. Adopting the National Plan or Strategy for rare diseases as a comprehensive document defining the needs in the country with regard to the rare diseases.
2. The need to solve the problem of diagnosing rare diseases in the country and abroad at the expense of the Republic Health Insurance Fund, by defining which laboratories in the

country perform necessary analyses, followed by signing of protocols on cooperation laboratories abroad performing those analyses that cannot be performed in the country. Thus, the process of establishing a diagnosis would be facilitated.
3. The need to create a registry of rare diseases kept by the Institute of Public Health "Dr Milan Jovanović Batut", and also to create mechanisms enabling the patients from this registry to exercise to the full extent their rights in the domain of health care and social welfare.
4. Defining certain number of centres of excellence within health care institutions which are already treating some rare disease or a group of rare diseases. In this way, a basis would be created to stimulate a multidisciplinary approach to treating people suffering from rare diseases.
5. Amending a series of legal documents so as to enable complete recognition of the notion of rare diseases in the healthcare and social welfare systems, thus providing a non-discriminatory level of health care and social welfare for the persons with rare diseases.
6. The need for a more extensive and comprehensive collaboration among health care professionals treating rare diseases at all levels: from the collaboration between the institutions in the country to the regional and international cooperation.

Annexe I: Programme

The Final Programme

First National Conference on Rare Diseases

December 5 to 7, 2013, Holiday Inn Hotel, Belgrade

Thursday, 05.12.2013.

19:00 - 20:00	**Registration of participants**
20:00 - 21:30	Welcoming cocktail

Friday, 06.12.2013.

08:30 - 09:00	**Arrival and registration of participants**	
09:00 - 09:50	**Opening of the Conference** *Moderator:* ***Ana Stamenković*** *Studenica+Ravanica+Gračanica Halls*	
09:00 - 09:15	Opening of the Conference	**Prof. Dr. Slavica Đukić-Dejanović**, Minister of Health of the Republic of Serbia
09:15 - 09:30	Opening of the Conference, welcoming address	**Prof. Dr. Dušan Milisavljević**, President of the Health and Family Committee of the Parliament of Serbia
09:30 - 09:35	Welcoming address	**Dr. Jelena Begović**, acting director of the Institute for Molecular Genetics and Genetic Engineering
09:35 - 09:50	Opening of the Conference, welcoming address and presentation of the NORBS	**Jelena Milošević**, President of the National Organisation for Rare Diseases

		of Serbia (NORDS)
09:50 - 10:15	Coffee break	
10:15 - 12:45	**Plenary Session** Moderator: **Ana Stamenković** *Studenica+Ravanica+Gračanica Halls*	
10:15 - 10:25	Introduction and presentation of participants	Moderator: **Ana Stamenković**
10:25 - 10:55	Presentation of EURORDIS and EU recommendations in the area of rare diseases (interpretation provided)	**Yann Le Cam**, Executive Director of the EURORDIS
10:55 - 11:10	Presentation of the EUROPLAN project	**Vlasta Zmazek**, EURORDIS
11:10 - 11:25	Status of the National strategy for rare diseases in Serbia	**Prof. Dr. Svetozar Damjanović**, President of the Republican committee of experts for rare diseases at the Ministry of Health
11:25 - 11:40	Legislative framework for the National plan for rare diseases within the health care system	**Dr. Periša Simonović**, Secretary of State in the Ministry of Health of the Republic of Serbia
11:40 - 11:55	The social welfare system – current achievements and challenges	**Vladimir Pešić**, Assistant of the Minister in the Ministry of Labour, Employment and Social welfare policy of the Republic of Serbia
11:55 - 12:10	Role and significance of the National register for rare diseases	**Dr. Snežana Plavšić**, "Dr. Milan Jovanović Batut", the Institute for public health of Serbia
12:10 - 12:25	Role of the National Health Insurance Fund of the Republic of Serbia in developing and supporting the implementation of the National Plan for Rare Diseases	**dr Zoran Vlahović**, Executive Director of the National Health Insurance Fund of the Republuic of Serbia
12:25 - 12:45	Time for questions and answers	Moderator: **Ana Stamenković**
12:45 - 13:00	**Commercial presentation of the CELGENE Company** *Studenica+Ravanica+Gračanica Halls*	

13:00 - 14:30	Lunch	
14:30 -16:00	**Workshop 1:** The infrastructure and methodology necessary to develop and implement the National Plan for rare diseases - experiences from Croatia, perspective in Serbia *Studenica+Ravanica+Gračanica Halls*	
14:30 - 14:40	Introduction and presentation of participants	Moderator: **Davor Duboka** - NORBS
14:40 - 15:00	Development of the National Plan for rare diseases in Croatia	**Prof. Dr. Ingeborg Barišić** – President of the Commission for development of the National Plan for RD, Croatia
15:00 - 15:20	Significance of genetic screening within the National strategy for rare diseases in Serbia	**Prof. Dr. Svetozar Damjanović** - President of the Republican committee of experts for rare diseases at the Ministry of Health
15:20 - 16:00	Discussion and conclusions of the workshop	Moderator: **Davor Duboka** - NORBS
14:30 - 16:00	**Workshop 2:** Strengthening the rare diseases patients and patients' assiciations – experiences from this country and the region *Ostrog+Žiča+Mileševa Halls*	
14:30 - 14:45	By means of activism up to a higher-quality life	**Jelena Milošević** – NORBS
14:45 - 14:55	In search for solutions	**Vlasta Zmazek** – Croatian Association for Rare Diseases
14:55 - 15:05	Presentation of activities of the Association for bullous epidermolysis DEBRA	**Mira Grujić Brojčin –** Association for bullous epidermolysis
15:05 - 15:15	Presentation of activities of the ''Life Challenges'' Association, the FYR of Macedonia	**Vesna Aleksovska** – ''Life Challenges'' Association, the FYR of Macedonia

15:15 - 16:00	Work in teams	Moderators: **Jelena Milošević** – NORBS; **Vlasta Zmazek** – Croatian Association for Rare Diseases; **Mira Grujić Brojčin** – Association for bullous epidermolysis - DEBRA; **Vesna Aleksovska** – Association ''Life Challenges'', the FYR of Macedonia
16:00– 16:30	Coffee break	
16:30 – 18:30	**Workshop 3:** Standards of care of patients suffering from rare diseases and Expert Centres *Studenica+Ravanica+Gračanica Halls*	
16:30 - 16:40	Introduction and presentation of participants	Moderator: **Mirjana Grujić Brojčin** - NORBS
16:40 - 16:55	From first steps to models (ten-year experience of the Fabri Centre, Slovenia)	**Dr. Bojan Vujkovac** – Fabri Centre at the General Hospital, Slovenj Gradec, Slovenia
16:55 - 17:10	Problems in diagnostics and therapy of patients with congenital diseases of metabolism in the territory of Serbia	**Dr. Adrijan Sarajlija** - "Dr. Vukan Čupić", the Institute for mother and child health care
17:10 - 17:25	Rare diseases in neurology: how we have functioned without expert centres	**Prof. Dr. Marina Svetel** – Clinic for Neurology at the Clinical Centre of Serbia (KCS)
17:25 - 17:55	EB House Austria & EB-CLINET : The expert centre and model for making the European referential network for genodermatosis in Austria (interpretation from English provided)	**Dr. Gabriela Pohla-Gubo** - EB Haus, Austria
17:55 - 18:10	EBH in Serbia: Diagnostic and therapeutic challenges	**Dr. Svetlana Popadić** – The Institute for dermatoveneralogy at the KCS
18:10 - 18:20	The different among the same – can it be rarer of the rarer? Presentation of two cases	**Dr. Ivan Pećin** – The Faculty of Medicine of the Zagreb University, the Institute for metabolic diseases at the KBC Zagreb, Croatia

18:20 - 18:30	Discussion and conclusions of the workshop	Moderator: **Mirjana Grujić Brojčin** - NORBS
16:30 – 18:00	**Workshop 4:** Definition, codification and listing of rare diseases *Ostrog+Žiča+Mileševa Halls*	
16:30 - 16:40	Introduction and presentation of participants	Moderator: **Dragana Koruga** - NORBS
16:40 - 16:55	Development of the Register for rare diseases in Croatia: How it was started and how far we have arrived	**Prof. Dr. Ingeborg Barišić** – President of the Committee for drafting the National Plan for Rare Diseases of Croatia
16:55 - 17:10	Primary immunodeficiencies in Serbia – history, possibilities and limitations	**Prof. Dr. Srđan Pašić** – Head of the department for immunology, "Dr. Vukan Čupić", the Institute for mother and child health care
17:10 - 17:25	Collection, validation and extending information about rare diseases – experience of ORPHANET, the European data base that contains relevant information about diagnostic tests, medical specialists, medical treatment centres and medicaments - orphans	**Dr. Maja Stojiljković Petrović** – The Institute for Molecular Genetics and Genetic Engineering
17:25 - 17:40	Methodology of introduction of the National register for rare diseases in Serbia	**Dr. Snežana Plavšić** - "Dr. Milan Jovanović Batut", the Institut for public health of Serbia
17:40 - 18:00	Discussion and conclusions of the workshop	Moderator: **Dragana Koruga** - NORBS
19:00 - 20:30	**The city sightseeing tour by bus (optional)**	
20:30	**Formal dinner** The Crystal Hall at the Hyatt Regency Hotel	

Saturday, 07.12.2013.

09:00 - 11:00	**Workshop 5:** Scientific research on rare diseases *Studenica+Ravanica+Gračanica Halls*	
09:00 - 09:10	Introduction and presentation of participants	Moderator: **Marija Joldić** - NORBS
09:10 - 09:25	Molecular diagnostics of rare diseases	**Dr. Sonja Pavlović** – The Institute for Molecular Genetics and Genetic Engineering
09:25 - 09:40	The project of screening to Fabry's disease in Serbia	**Dr. Goran Čuturilo** – The ''Tiršova'' University Children's Hospital
09:40 - 09:55	Use of bio-markers in diagnostics and following therapeutic answer with Gaucher's disease	**Dr. Zorica Šumarac** – The Centre for medical biochemistry at the Clinical Centre of Serbia (KCS)
09:55 - 10:10	Mucopolysaccharidosis: Challenges on the way to diagnostics	**Prof. Dr. Ksenija Fumić** – The Zagreb Clinical Hospital Centre, Croatia
10:10 - 10:25	Medical, legal and ethical aspects of cell therapy in paediatrics	**Dr. Dragana Vujić** – "Dr. Vukan Čupić", the Institute for mother and child health care
10:25 - 11:00	Discussion and conclusions of the workshop	Moderator: **Marija Joldić** - NORBS
09:00 - 11:00	**Workshop 6:** Patients' rights within the system of health care and social welfare policy in Serbia *Ostrog+Žiča+Mileševa Halls*	
09:00 - 09:10	Introduction and presentation of participants	Moderator: **Jelena Milošević** - NORBS
09:10 - 09:25	Rights of patients suffering from rare diseases within the system of health care policy in Serbia	**Dr. Nebojša Jokić**, Assistant Minister in the Ministry of Health of the Republic of Serbia
09:25 - 09:40	Rights and services within the social welfare system in Serbia	**Jasmina Ivanović,** The Ministry of labour, employment and social welfare
09:40 - 09:55	Legal framework for status of persons suffering from rare diseases	**Dr. Damjan Tatić** – The United Nations Committee for disabled persons

09:55 - 10:10	The status of patients suffering from rare diseases from the aspect of the medical law	**Dr. Hajrija Mujović Zornić** – The Institute of Social Sciences – SUPRAM
10:10 - 10:25	Rights of patients in practice	**Marina Mijatović** – ''Legal Scanner'', the nongovernmental organisation
10:25 - 11:00	Discussion and conclusions of the workshop	Moderator: **Jelena Milošević** - NORBS
11:00 - 11:30	Coffee break	
11:30 - 12:50	**Presentation of conclusions of the workshops and conclusions of the Conference** *Studenica+Ravanica+Gračanica Halls*	
12:50 - 13:00	**Closing of the Conference** *Studenica+Ravanica+Gračanica Halls*	
13:00 - 14:00	**Debrief meeting** *Hilandar Hall*	
13:00 - 14:30	Lunch	
14:30	**Regular annual meeting of the NORBS** (for NORBS members) *Mileševa Hall*	

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EURORDIS
Rare Diseases Europe

Annexe II: List of Institutions

1. Ministry of Health of the Republic of Serbia
2. Committee for Health and Family, the Assembly of Serbia
3. State Secretary in the Ministry of Health of the Republic of Serbia
4. Ministry of Labour and Social Policy
5. National Health Insurance Fund
6. ”Batut” Institute of Public Health
7. Commission for development of the National Plan for RD Croatia
8. Commission for Rare Diseases at the Ministry of Health of the Republic of Serbia
9. ‘’Life Challenges’’ Association, FYR of Macedonia
10. Debra, Croatia
11. Rett syndrome
12. Muscular Dystrophy Union, Serbia (NORDS)
13. Debra, Serbia (NORDS)
14. Fabry Centre, Slovenia
15. EB House, Austria
16. Department for Metabolism, the Institute for Mother and Child, Belgrade Department for Metabolism, the Institute for Mother and Child, Belgrade
17. ”Bezanijska Kosa” Medical Centre, Belgrade
18. Commission for development of the National Plan for RD, Croatia
19. Institute for Mother and Child, Belgrade
20. The Institute of Molecular Genetics and Genetic Engineering, Belgrade
21. Representative of the ”Batut” Institute of Public Health

Annexe III: List of participants

Name	Organisation	Role	Stakeholder group
Dr Periša Simonović	Ministry of Health	Secretary of State	Politician
Gordana Pođanin	Ministry of Health	Sector for Health Insurance	Politician
Nebojša Jokić	Ministry of Health	Sector for European Integration and International Cooperation	Politician
Prof Dr Dušan Milisavljević	National Assembly of the Republic of Serbia	Chairman of the Board of Health and Family	Politician, Clinician/GP
Jasmina Ivanović	Ministry of Labour, Employment and Social Policy	Sector for Improvement Social Protection Systems	Politician
Vladimir Pešić	Ministry of Labour, Employment and Social Policy	Assistant of Minister	Politician
Dr Jelena Begović	Institute of Molecular Genetics and Genetic Engineering	Acting Director	Healthcare Professional (other than clinician or GP)
Dr Zoran Vlahović	Republic Health Insurance Fund	Executive Director	Insurer
Dr Marija Kalaba	Republic Health Insurance Fund	Sector for Procurement	Insurer
Dr Snezana Plavšić	Institute for Public Health 'Dr Milan Jovanović Batut'	Epidemiology	Healthcare Professional (other than clinician or GP)
Dr Damjan Tatić	The UN Committee on the Rights of Persons with Disabilities	Coordinator	Other
Dr Hajrija Mujović Zornić	Institute of Social Sciences, SUPRAM		Medical /Learned society
Marina Mijatović	NGO Law Scanner	Director	Other
Mira Armour	Celgene	Rpresenative	Industry
Gordana Pančić Lenarčič	Celgene	Area Director	Industry
Nikola Soćanac	Celgene	Country Representative Serbia	Industry
Sonja Ermacora	Sanofi/Genzyme	Head of Genzyme Adriatic MCO	Industry
Alen Škrbec	Sanofi/Genzyme	PGH Operational Manager Alpe Adria Region	Industry

Adriana Ćimić	Sanofi/Genzyme	Market Access Manager Alpe Adria Region	Industry
Tatjana Marjanović	Sanofi/Genzyme	Product Manager	Industry
Dušan Drenić	Sanofi/Genzyme	Regional Manager	Industry
Žana Goić Petričević	Solpharm Adriatic/Shire	Commercial Affairs Croatia	Industry
Marko Matulović	Solpharm Adriatic/Shire	Sales Manager Croatia	Industry
Gordana Radivojević	Solpharm Adriatic/Shire	Area Director Serbia	Industry
Dušan Gužvica	Solpharm Adriatic/Shire	Medical Representative Serbia	Industry
Mirko Ristanovic	Pfizer	Pricing and Reimbursement Manager Serbia	Industry
Pavle Marjanović	Actavis d.o.o.	General Manager	Industry
Sanja Panješković	Glaxo Smith Kline	Inernal Communication Coordinator PA to PM	Industry
Ivana Đorđević Siđanin	Providens d.o.o.	General Manager	Industry
Nevena Obradović	Polifarm	Medical Representative Serbia	Industry
Sonja Gvozdenović	Unifarm Medicom	Medical Representative Serbia	Industry
Dr Božica Kecman	Institute for Health Protection of Mother and Child Serbia,' Dr Vukan Cupic'	Department for Genetics and Metabolism	Clinician/GP
Dr Adrijan Sarajlija	Institute for Health Protection of Mother and Child Serbia,' Dr Vukan Cupic'	Department for Genetics and Metabolism	Clinician/GP
Dr Srđan Pašić	Institute for Health Protection of Mother and Child Serbia,' Dr Vukan Cupic'	Department of Immunology	Clinician/GP
Dr Goran Ristić	Institute for Health Protection of Mother and Child Serbia,' Dr Vukan Cupic'	Department of Immunology	Clinician/GP
Dr Sergej Prijić	Institute for Health Protection of Mother and Child Serbia,' Dr Vukan Cupic'	Department of Cardiology	Clinician/GP

Dr Dragana Vujić	Institute for Health Protection of Mother and Child Serbia,' Dr Vukan Cupic'	Deparment of bone marrow transplantation with laboratory for criobiology	Clinician/GP
Dr Goran Čuturilo	University Children Hospital Tiršova	Head of Genetics Department	Clinician/GP
Prof Dr Svetozar Damjanović	Clinical Center Serbia, Belgrade	Proffesor of Internal Medecine, Head of Endocrinooncology	Clinician/GP, Medical /Learned society
Prof Dr Marina Svetel	Clinical Center Serbia, Belgrade, Neurology	Neurologist	Clinician/GP
Prof Dr Zorica Šumarac	Clinical Center Serbia, Belgrade	Laboratory of Medical Biochemistry, Deputy Director	Healthcare Professional (other than clinician or GP)
Dr Svetlana Popadić	Clinical Center Serbia, Belgrade, Dermathology	Dermatologist, spec. EB	Clinician/GP
Mirjana Tomić	Clinical Center Serbia, Belgrade, Dermathology	Nurse	Healthcare Professional (other than clinician or GP)
Svetlana Balotić	Clinical Center Serbia, Belgrade, Dermathology	Nurse	Healthcare Professional (other than clinician or GP)
Zorica Jevđenijević	Clinical Center Serbia, Belgrade, Dermathology	Nurse	Healthcare Professional (other than clinician or GP)
Prof Dr Dragoslava Đerić	Clinical Center Serbia, Belgrade, ORL	Hearing and Speech therapist	Clinician/GP
Sr Zorica Šporčić	Clinical Center Bežanijska kosa, Belgrade	Immunology, PID	Clinician/GP
Prof Dr Vedrana Milić Rašić	Clinical Center Serbia, Belgrade, Hematology	Neurologist	Clinician/GP
Prof Dr Nada Suvajdžić Vuković	Clinical Center Serbia, Belgrade, Hematology	Hematologist	Clinician/GP
Jovanka Tatomir	VMA	Nurse	Healthcare Professional (other than clinician or GP)
Dr Sonja Pavlović	Institute of Molecular Genetics and Genetic Engineering	Principal Investigator	Academic/Researcher
Dr Maja Stojiljković Petrović	Institute of Molecular Genetics and Genetic Engineering	Laboratory for Molecular Biomedicine	Academic/Researcher
Dr Kristen Klaassen	Institute of Molecular Genetics and Genetic Engineering	Researcher	Academic/Researcher

Dr Anita Skakić	Institute of Molecular Genetics and Genetic Engineering	Researcher	Academic/Researcher
Dr Aleksandra Nestorović	Institute of Molecular Genetics and Genetic Engineering	Researcher	Academic/Researcher
Dr Nikola Kotor	Institute of Molecular Genetics and Genetic Engineering	Researcher	Academic/Researcher
Dr Marina Anđelković	Institute of Molecular Genetics and Genetic Engineering	Researcher	Academic/Researcher
Dr Tatjana Kostić	Institute of Molecular Genetics and Genetic Engineering	Researcher	Academic/Researcher
Dr Branislava Medić	Farmacology Institute	Researcher	Academic/Researcher
Dr Dušanka Savić-Pavićević	Faculty of Biology	Researcher	Academic/Researcher
Prof Dr Jadranka Jovanović Privrodski	Institute for Health Protection of Children and Youth Vojvodina	Genetics	Clinician/GP, Medical /Learned society
Dr Ivana Kavečan	Institute for Health Protection of Children and Youth Vojvodina	Genetics	Clinician/GP
Dr Milan Obrenović	Institute for Health Protection of Children and Youth Vojvodina	Laboratoty of Medical Biochemistry	Clinician/GP
Prof Dr Ljiljana Hadnađev	Clinical Center Vojvodina	Gastroenterology and Hepatology	Clinician/GP
Dr Vesna Bogićević	Clinical Center Niš, Pediatrics	Hemato/oncology	Clinician/GP
Dr Tatjana Stanković	Clinical Center Niš, Pediatrics	Immunology and genetics	Clinician/GP
Dr Dragana Ilić	Clinical Center Niš, Pediatrics	Gastroenterology	Clinician/GP
Dr Irena Marsenić	Clinical Center Niš, Pediatrics	Pulmology	Clinician/GP
Dr Hristina Stamenković	Clinical Center Niš, Pediatrics	Immunology and genetics	Clinician/GP
Dr Ljiljana Branković	Clinical Center Niš	Genetics	Clinician/GP
Dr Radovan Milićević	Clinical Center Niš	Genetics	Clinician/GP
Dr Irena Ćojbašić	Clinical Center Niš	Hematology	Clinician/GP
Dr Vesna Nikolić	Clinical Center Niš	Hematology	Clinician/GP

Dr Lana Mačukanović Golubović	Clinical Center Niš	Hematology	Clinician/GP
Valentina Kostić	Clinical Center Niš	Nurse	Clinician/GP
Dr Maja Slavković Jovanović	Clinical Center Niš	Pulmology	Clinician/GP
Dr Ljiljana Perović	Clinical Center Niš	Pulmology	Clinician/GP
Dr Simonida Šeškar Stojančov	Clinical Center Niš	Endocrinology	Clinician/GP
Dr Aleksandar Mihajlović	Clinical Center Niš	Cardiology	Clinician/GP
Dr Siniša Ristić	Clinical Center Niš	Neurologist	Clinician/GP
Dr Snežana Ristić	Clinical Center Niš	ORL	Clinician/GP
Dr Dragana Simić	Clinical Center Niš	ORL	Clinician/GP
Dr Dragan Mihailović	Clinical Center Niš	Patology	Clinician/GP
Prof Dr Žaklina Mijović	Clinical Center Niš	Patology	Clinician/GP
Dr Miodrag Lazić	Clinical Center Niš	Surgery	Clinician/GP
Dr Marija Dimitrijević	Clinical Center Niš	Surgery	Clinician/GP
Dr Mihajlo Đorđević	Clinical Center Niš	Surgery	Clinician/GP
Dr Sunčica Mihajlović	Clinical Center Niš	ER surgery	Clinician/GP
Dr Nebojša Đorđević	Clinical Center Niš	Surgery	Clinician/GP
Dr Tatjana Ristić	Clinical Center Niš	Laboratoty of Medical Biochemistry	Clinician/GP
Dr Biljana Stošić	Clinical Center Niš	Anesthesiologist	Clinician/GP
Dr Dragana Stanković-Đorđević	Clinical Center Niš	Anesthesiologist	Clinician/GP
Dr Biljana Kocić	Clinical Center Niš	Epidemiology	Clinician/GP
Ivana Kostov	Clinical Center Niš	Nurse	Healthcare Professional (other than clinician or GP)
Ljubica Cvetković	Clinical Center Niš	Nurse	Healthcare Professional (other than clinician or GP)
Nataša Sekulović	Clinical Center Niš	Nurse	Healthcare Professional (other than clinician or GP)

Slađana Miljković	Clinical Center Niš	Nurse	Healthcare Professional (other than clinician or GP)
Slađana Tričković	Clinical Center Niš	Nurse	Healthcare Professional (other than clinician or GP)
Sonja Keča	Clinical Center Niš	Nurse	Healthcare Professional (other than clinician or GP)
Ivana Stamenković	Clinical Center Niš	Nurse	Healthcare Professional (other than clinician or GP)
Ana Lazić	Clinical Center Niš	Nurse	Healthcare Professional (other than clinician or GP)
Dr Dejan Janjić	General Hospital Leskovac	Doctor	Clinician/GP
Dr Gabriela Pohla-Gubo	EB House Austria	EB	Clinician/GP
Dr Bojan Vujkovac	Fabry Center Slovenia	Head of Fabry Center	Clinician/GP
Dr Andrea Cokan Vujkovac	Fabry Center Slovenia	Nefrology	Clinician/GP
Prof Dr Ingeborg Barišić	Children's Hospital Zagreb, Croatia	Internist	Clinician/GP
Prof Dr Ksenija Fumić	Clinical Center REBRO Zagreb, Croatia	Laboratory of Medical Biochemistry	Clinician/GP
Dr Ivan Pećin	Clinical Center REBRO Zagreb, Croatia	Internist	Clinician/GP
Dr Mensuda Hasanhodžić	Clinical Center Tuzla, BIH	Pediatrics and Genetics	Clinician/GP
Prof Dr Mirjana Ivanović	Faculty of Stomatology	Dentist for Children with Special Needs	Clinician/GP
Jasmina Arsić	Pharmacy Vranje	Pharmacist	Healthcare Professional (other than clinician or GP)
Prof Dr Dušanka Krajnović	Faculty of Pharmacy	Proffesor	Healthcare Professional (other than clinician or GP)
Dr Siniša Pavlović	Hospital	Doctor	Clinician/GP
Dr Nada Pevčević	BELMEDIC private practice	Doctor	Clinician/GP
Dr Miloš Stojanović	Emergency medical care Belgrade	Doctor	Clinician/GP
Jelena Milošević	NORBS	President	Patient representative

Davor Duboka	NORBS	Executive Director	Patient representative
Dragana Koruga	POsPID	President	Patient representative
Nenad Stojnić	POsPID	Member	Patient representative
Vesna Tonev	POsPID	Member	Patient representative
Snežana Obradović	POsPID	Member	Patient representative
Irina Čepinac Ban	"Zvončica" The Association of Parents of Children with malignant diseases		Patient representative
Sandra Pavlović	Debra	President	Patient representative
Mirjana Grujić-Brojčin	Debra	Board Member	Patient representative
Mirjana Vukadinović	Debra	Board Member	Patient representative
Stanislav Prvulović	Debra	Member	Patient representative
Stanoje Prvulović	Debra	Member	Patient representative
Mijo Vesović	Debra	Member	Patient representative
Snežana Janošević	Debra	Board Member	Patient representative
Marija Joldić	Hunter Syndrome Association Serbia	President	Patient representative
Rada Simeunović	Hunter Syndrome Association Serbia	Vice president	Patient representative
Danijela Radulović	Hunter Syndrome Association Serbia	Vice president	Patient representative
Dragana Miletić Lajko	MPS Srbija	Board Member	Patient representative
Boštjan Herlič	MPS - Slovenia		Patient representative
Nataša Herlič	MPS - Slovenia		Patient representative
Goran Ilić	Friedreich Ataxia Association Serbia	President	Patient representative

Ana Ilić	Friedreich Ataxia Association Serbia	Member	Patient representative
Ljiljana Ilić	Friedreich Ataxia Association Serbia	Member	Patient representative
Gordana Gajić	Friedreich Ataxia Association Serbia	Member	Patient representative
Slavica Milošević	Friedreich Ataxia Association Serbia	Member	Patient representative
Dragan Đurović	CF Serbia	President	Patient representative
Darinka Šulić	Gaucher Association Serbia	President	Patient representative, Clinician/GP
Jadranka Vujin	Gaucher Association Serbia	Board Member	Patient representative
Snežana Ćosić	Gaucher Association Serbia	Board Member	Patient representative
Biljana Jovanović	Gaucher Association Serbia	Board Member	Patient representative
Marina Stanišić	Gaucher Association Serbia	Board Member	Patient representative
Nenad Pavlović	Gaucher Association Serbia	Member	Patient representative
Predrag Bakić	Muscular Dystrophy Association Serbia	President	Patient representative
Radovan Pavlović	Muscular Dystrophy Association Serbia	Board Member	Patient representative
Biljana Đorđević	Muscular Dystrophy Association Niš	President	Patient representative
Marina Savović	Muscular Dystrophy Association Niš	Member	Patient representative
Aleksandra Panović	Muscular Dystrophy Association Vovodina	Member	Patient representative
Gorjana Ajzinberg	Rare Tumors Patient Association	President	Patient representative
Goran Timotijević	Rare Tumors Patient Association	Member	Patient representative
Jelena Vuksić	Rare Tumors Patient Association	Member	Patient representative, Clinician/GP
Velibor Vuksić	Rare Tumors Patient Association	Member	Patient representative

Zorica Jandrić	Rare Tumors Patient Association	Member	Patient representative
Jasminka	PKU Serbia	Member	Patient representative
Miodrag	PKU Serbia	Member	Patient representative
Stevan Ilić	NORBS	Member	Patient representative
Božo Ilić	NORBS	Member	Patient representative
Miloš Pavić	NORBS	Member	Patient representative
Radica Pavić	NORBS	Member	Patient representative
Jelena Zelenović	NORBS	Member	Patient representative
Lenka Zelenović	NORBS	Member	Patient representative
Dragica Maksimović	CS/WS		Patient representative
Saša Košutić	Wilson Association	President	Patient representative
Vladan Vukadinović	Parent of undiagnosed child		Patient representative
Sanja Kotur	Association of myelofibrosis	President	Patient representative
Veroslav Jovanović	Parent of undiagnosed child		Patient representative
Vesna Aleksovska	Life with Challenges	President	Patient representative
Vlasta Zmazek	Debra Croatia	President	Patient representative