EUROPLAN
European Project for Rare Diseases National Plans Development
Coordinated by the Italian National Centre for Rare Diseases
Italian National Institute of Health
2012-2015

Πανελλήνια Ένωση Σπανίων Παθήσεων
Greek Alliance for Rare Diseases

EURORDIS
Rare Diseases Europe

GREECE

EUROPLAN NATIONAL CONFERENCE

FINAL REPORT

1 December 2012, Athens

Co-funded by
the Health Programme
of the European Union

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.

I. General information

Country	**Greece**
Date & place of the National Conference	**1st December 2012, Eugenides Foundation, Athens**
Website	
Organisers	**Greek Alliance for Rare Diseases (Acronym PESPA)**
Members of the Steering Committee	N. Karapanos: Representative of the Ministry of Health E. Gavriil: Head of The Institute of Pharmaceutical Research and Technology (IFET) E. Kanavakis: Professor of Genetics, University of Athens Dr A. Kypreos: Head of South East Europe / General Manager Greece & Cyprus, GENZYME M. Lambrou: Chair of the Greek Alliance for RD (PESPA) and the Tuberous Sclerosis Association of Greece I. Laina: Representative of the Hellenic Center for Disease Control & Prevention (KEELPNO) Christos Lionis: Vice President of the National Council of Public Health (E.SY.D.Y.) E. Michelakakis: Greek Representative for ORPHANET Andreas Seretis: President of the Central Health Council (KE.S.Y.) I. Tountas: Chair of the Greek Organization for Medical Products (EOF) Andreas Tsouros: President of the National Council of Public Health (E.SY.D.Y.) K. Frouzis (Chair of the Association of Greek Pharmaceutical Companies –SFEE)
Members of the Organizing Committee	Marianna Lambrou (Chair of the Greek Alliance for RD - PESPA) Vicky Biliou (Chair of the Greek PWS Organization & Secretary of PESPA) D. Yannoukakos (Researcher at NCSR DEMOKRITOS & Deputy Chair of PESPA) G. Voutsinas (Researcher at NCSR DEMOKRITOS & Treasurer of PESPA)

	Christos Manolakakis: President of the Association for Patients with Primary Immunodeficiencies, "Harmony" & Board member of PESPA) Jan Traeger-Synodinos (Assoc. Prof. of Genetics, Athens University & member of PESPA Board) Efterpi Floka (RD patient and member of PESPA Board) Dimitrios Synodinos (BoD EURORDIS & Associate of PESPA Board)
Names and list of Workshops	**I. The Access of Patients with Rare Diseases to Diagnosis and Medical Care (Theme 4.7 & 5)** **II. Social Care for Patients with Rare Diseases (Theme 6)** **III. Rare Diseases Reference Centers (Theme 4)** **IV. Rare Diseases Registries in Greece (Theme 2 and 3.6)**
Chairs and Rapporteurs of Workshops	**I. Chair: G. Voutsinas, Rapporteurs: C. Manolakakis** **II. Chair: V. Biliou, Rapporteur: G. Makris** **III. Chairs: D. Synodinos, J. Traeger-Synodinos, Rapporteur A. Gliati** **IV : Chairs: M. Lambrou, D. Yannoukakos, Rapporteur : E. Floka**
Annexes	**-Programme (English Translation)** **-Press Release**

Main Themes

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

This theme was not addressed during the Greek Europlan II conference since there has been no progress on the side of the Greek State to initiate the application of the Greek National Plan, which has remained on paper only.

Theme 2 and 3.6 - Definition, codification and inventorying of RD, including RD Patient Registries in Greece (Greek Europlan II Conference WG IV)

Chairs : M. Lambrou; Dr. D. Yannoukakos; Rapporteur: E. Floka
Facilitator (Chair) : M. Lambrou; Dr. D. Yannoukakos
Present at WG with active participation were:

- Mrs M. Lambrou, President of the Greek Alliance for Rare Diseases, and the Tuberous Sclerosis Association of Greece
- Dr E. Kanavakis, Professor of Medical Genetics, University of Athens, Greece
- Dr V. Sfyroeras, ex-Director of the central computer of Electronic Government of Social Welfare – IDIKA
- Dr N. Koutsostathis, Specialist of Hereditary Angioedema
- Dr G. Anastasiadis, Director of Paediatrics Clinic at Children's Hospital Aghia Sophia
- Dr A. Kypreos, Head of South East Europe / General Manager Greece & Cyprus at GENZYME
- Dr K. Souliotis, Assist. Professor of Health Policy, Faculty of Social Sciences, Univ. of Peloponnese
- Mrs E. Floka, member of the Greek Alliance for Rare Diseases BoD
- Members of patients associations as well patients or relatives and students.

EUROPLAN Indicators for Definition, Codification and Inventorying of RD

EUROPLAN Indicators part 1

ACTIONS	INDICATORS	TYPE	ANSWERS (Greece)
To officially adopt the EC RD definition (no more than 5 cases/10,000 inhabitants)	Adoption of the EC RD definition	Process	• **Not yet**
To include the best Rare Diseases classification currently existing into the public health care related services	Type of classification used by the health care system	Process	• **ICD-10**

EUROPLAN Indicators part 2

ACTIONS	INDICATORS	TYPE	ANSWERS (Greece)
To include the best Rare Diseases classification currently existing into the public health care related services	Developing policies for recognising RD by the care information systems	Process	• **Not existing, not clearly stated**
Defining a surveillance system based on a patient outcomes registry	Registering activity	Process	• **No official registry yet**
	Number of diseases included	Outcomes	

2.1. Definition of RD

Question 1

▪ Is the EU official definition (RD are those affecting up to 5 out of 10 000 person) used in your country?

Answer

▪ Officially, no. Used informally by the people who already know the analogy of 5/10.000

Suggestion

▪ Be legislated by the Greek Parliament with law of state and the relative Ministries commit for its functional adoption: (1) Health and Social Solidarity, (2) Employment and Social Insurance and (3) Economy, Competitiveness and Shipping

Question 2

▪ Are there alternative or more specific definitions used instead or in addition?

Answer

▪ No

2.2. Classification and traceability of RDs in the national health system

Question 1

- What classification system is used in your country? ICD9, ICD10, SNOMED, OMIM, ORPHAN...

Answer

- The ICD10 classification was officially adopted 3 years ago, but it is not used yet in the central system of the National Health System.

Question 2

- For which purpose is (are) the classification system(s) used, e.g. surveillance, reimbursement, provision of social support, etc.

Answer

The goal is to be used for surveillance, reimbursement and provision of social support but very limited use is made.

Suggestion

- Involved Ministries should promptly exercise pressure on state and private supervised entities for adopting ICD10 in practice at all levels of the National Health and Welfare system.
-

Question 3

- Is your country prepared to adopt the WHO-led system, the ICD-11, recommended by the EU in the Council Recommendation on RD, when ready (2014)?

Answer

- No.

Suggestion

- Adoption of ICD10 in practice must proceed, coupled with a change in the attitude vis-à-vis disease inventorying that will be the foundation for ICD11 acceptance.

Question 4

- What level of awareness and knowledge do healthcare professionals have of the RD classification and codification? What can be done to improve it?

Answer

- They are not well informed.

Suggestions

- Implementation of ICD10 in daily clinical practice will help systemize the inventorying process and in turn will promote the level of knowledge and awareness on RD of health professionals. Moreover, it is also recommended that Ministry's and Patient Associations' functionaries would take initiatives, during medical congresses, by means of relevant printed leaflets, by setting up seminars in Medical Schools and/or hospitals, by providing information via the Athens and Thessaloniki Medical Societies, as well their respective printed publications.

2.3. Codification of RD and traceability in national health system

Question 1

▪ Are there official lists of RD in your country? Is there an official governmental RD registry? And/or specific RD databases e.g. held by Centres of Expertise? Are there RD surveillance projects or programmes (e.g. sentinel programmes, surveys)?

Answer

▪ Official lists of RD do not exist in Greece. However there are four different kind of registries that could be useful: 1. The unique identification number (AMKA) recently adopted by the National Health and Welfare System. The State registry run by the Center for Disease Control and Prevention (KEELPNO) is still in a infant state without official results 2. Registries of patient organizations e.g. the one of the Greek Alliance for Rare Diseases – PESPA, which is currently the broadest registry in Greece, which through participating in the EURORDIS network of RD, hopes to support a complete database 3. Registries of researchers and medical doctors and 4. Registries of pharmaceutical companies.

Question 2

▪ What kind of initiatives should be taken or reinforced in your country?

Answer

▪ The creation of a Registry of Registries is very important. The collaboration of all four above stakeholders will be a critical step in order to improve the quality and insure the viability of all existing registries. To ensure sustainability of inventorying, a certain amount of state funding must be provided for.

Question 3

▪ Do these registries and programmes receive government support?

Answer

▪ Existing non-state, individual or collective, inventories are not being supported by the state. A state pilot registry, run by the Center for Disease Control and Prevention (KEELPNO), covering just four RDs*, is receiving government support but no serious progress has been made in the last year, which means that there is still no broad government registry. These four RDs include: Thalassaemia, Cystic Fibrosis, Haemophilia and Gaucher Disease. Cystic Fibrosis, Haemophilia and Gaucher Disease are represented by Patient Associations in PESPA.

Question 4

▪ How to ensure, through appropriate funding mechanisms, the long-term sustainability of registries and databases?

Answer

▪ As mentioned above, funding must derive from state sources, since no exuberant amounts of money are needed. If this is not feasible, the option of financing registries and/or databases by private sources must be examined, once eventual requirements by individuals are considered.

Question 5

▪ Does your country participate to the development of a EU inventory of RD as recommended in the Council Recommendations on RD?

Answer

▪ Our country only marginally participates in the EU-driven RD patient inventorying, through EPIRARE. However, the Children Health Institute's Division of Genetics, as formal representative of Greece in the ORPHANET world network, collects data on Greece that are forwarded to update the above directory. The ORPHANET directory contains information on European services on RD with respect to clinics, biochemical and molecular laboratories, research activities and active patient associations.

2.4. Training healthcare professionals to recognise and code RD

This was not discussed during the Greek Europlan II meeting.

2.5. Information and training

Question 1

▪ What are the existing information sources in the country? Are they of good quality? Do they receive public funding or Patients Org. funding?

Answer

▪ Scarce official and self-declared Centers of Expertise (state-funded but without a role to inform the public on RD treatment) and Patient Associations (non state-funded), including PESPA and its Patient Association Members, which provide information regarding their respective RD. Also, as mentioned above, the Children Health Institute's Division of Genetics, as formal representative of Greece in the ORPHANET network, collects data on Greece that are forwarded to update the above directory. Information provided is usually of high quality, although there is always room for improvement.

Suggestion

The Orphanet network still awaits translation into the Greek language.

Question 2

▪ Is there a national official website for RD in the country?

Answer

▪ No.

Suggestion

▪ To establish an official national website on RD in our country funded by the Ministry of Health and Social Solidarity and potentially by private entities. PESPA has already taken a non-state funded initiative on behalf of the RD patients.

Question 3

▪ Are there help lines for both patients and healthcare professionals? Are they known to the public?

Answer

▪ In terms of patient help lines, the telephone numbers of patient associations are the ones used for that purpose, and PESPA plays an important role in informing and supporting RD

patients and patient organizations. There are no help lines for health professionals. Patient associations are not particularly known to the wider public despite their efforts to gain exposure.

Suggestion

- Establishment of a telephone help line, bearing a phone number compatible with operating principles of such lines in other European countries. To do so, subject to detailed feedback by colleagues from other EU countries, with relevant experience, a task force should be formed which all interested parties should take part in (patient groups, clinical doctors, psychologists, etc), to determine such help lines' operating principles and rules of partnerships among interested parties, and to also appoint persons in charge of each specific action (psychological support, medical information).

Theme 2 General conclusions/suggestions

Official lists of RD do not exist in Greece. However there are four different kind of registries that could be useful: 1. Based on the unique identification number (AMKA) of every Greek citizen, which has recently been adopted by the National Health and Welfare System 2. Registries created by patient organizations, for example analogous to the one created by the Greek Alliance for Rare Diseases – PESPA 3. Registries of researchers and medical doctors, and, 4. Registries of pharmaceutical companies.

Due to the current fragmentation of RD registries in Greece, the creation of a Registry of Registries is deemed very important. The collaboration of all above stakeholders will be a critical step in order to improve the quality of registries and insure a viability of all existing registries.

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

This theme was not addressed during the Greek Europlan II conference since there has been no progress on the side of the Greek State to support funding for research on RD in Greece; there is no policy to map existing research resources, infrastructures and programmes for RDs, nor for dedicated RD research programmes and governance of RD research funds, nor for sustainability of research programmes on RD; nor for needs and priorities for research in the field of RDs; nor

for fostering interest and participation of national laboratories and researchers, patients and patient organisations in RD research projects, nor for RD research infrastructures and registries. Any EU and international collaboration on research into RD is sporadic and is based on the initiative of individual research groups. Specifically for RD, a couple of research projects have been funded through the E-Rare programme in the past.

Theme 4: Care for RDs - Centres of Expertise (CoE) (Greek Europlan Conference WGIII)

Stakeholder participants: J. Traeger –Synodinos, S. Youroukos, E. S. Doudounakis, E. Alataki - Papadopoulou
Chairs and Rapporteurs: D. Synodinos, N. Bazoura

Dr. J Traeger – Synodinos, DPhil
Present at the Work shop with active participation were:

- Dr. S. Youroukos (Pediatric neurologist, active in the field of RD)
- Dr. E Alataki-Papadopoulou (Assistant Professor, Pediatrics-Immunology, active in the field of RD)
- Dr. S. Doudounakis, (Pediatrician, Head of the Centre of Reference for clinical care of Cystic Fibrosis patients, St. Sophia Children's Hospital, Athens).
- Ms N. Vazoura representative of a patient organization (RETT syndrome).

4.1 Designation and evaluation of CoE

There is no policy for establishing CoE's at the national/regional level and no clearly defined quality criteria for CoEs.

EUROPLAN INDICATORS FOR CENTRES OF EXPERTISE

ACTIONS	INDICATORS	TYPE	ANSWERS (Greece)
Improve the quality of health care by defining: - appropriate centres with experience on RD - pathways that reduce the diagnosis delay and facilitate the best care and treatments	Existence of a policy for establishing centres of expertise at the national/regional level	Process	**• Not existing, not clearly stated**
	Number of centres of expertise adhering to the policy defined in the country	Outcomes	**Number of reference centres – >30 specialized depts or clinics but NOT reference centres with criteria of EURORDIS; THE ORGANIZATION KEELPNO IS IN THE PROCESS OF CREATING A REGISTER OF SPECIALIZED CLINICS CURRENTLY FUNCTIONING IN GREECE**

	Groups of rare diseases followed up in centres of expertise	Outcomes	**Covering only some rare diseases –a few diseases (SEE BELOW) I**

4.2 Scope and functioning of CoEs

There are DEPARTMENTS/CLINICS (not fully CoE's) for some RD's, including: Gaucher & Fabry, Histiocytosis, Hemophilia, Pulmonary Hypertension, Retinopathies, Cystic Fibrosis, Crohn's Disease, Congenital Cardiopathies, Keratoconus, Prader Willi, Hereditary Metabolic Disorders, Rheumatoid Arthritis, Primary Immunodeficiencies (Pediatric), Thalassemia, Sickle Cell Anemia.

These clinics are set-up in hospitals where all relevant patients in the specific city have to visit in order to receive diagnosis/treatment regarding their disease.

EUROPLAN INDICATORS FOR CENTRES OF EXPERTISE

ACTIONS	INDICATORS	TYPE	ANSWERS (Greece)
Improve the quality of health care by defining: - appropriate centres with experience on RD - pathways that reduce the diagnosis delay and facilitate the best care and treatments	Centres of expertise adhering to the standards defined by the Council Recommendations - paragraph d) of Preamble	Outcomes	**Percentage of centers of expertise adhered by the total of centers of expertise designed- NO GREEK CENTRES ADHERE TO ALL THE STANDARDS DEFINED BY THE COUNCIL OR EUCERD RECOMMENDATION**
	Participation of national or regional centres of expertise into European reference networks	Outcomes	**Index based on number of centres of expertise SOME GREEK CENTRES PARTICIPATE IN EUROPEAN REFERENCE NETWORKS BUT THERE IS NO CENTRAL REGSISTER FOR THEM**

4.3 Multidisciplinarity, healthcare pathways & continuity of care

- There are DEPARTMENTS/CLINICS (not fully CoE's) for some RD's, including: Gaucher & Fabry, Histiocytosis, Hemophilia, Pulmonary Hypertension, Retinopathies, Cystic Fibrosis, Crohn's Disease, Congenital Cardiopathies, Keratoconus, Prader Willi, Hereditary Metabolic Disorders, Rheumatoid Arthritis, Primary Immunodeficiencies (Pediatric), Thalassemia, Sickle Cell Anemia.
- A few of the existing DEPARTMENTS/CLINICS (not fully CoE's) are multidisciplinary, but most are not. Currently only a few CoEs for a few diseases (thalassemia and cystic fibrosis) support the transition of healthcare between pediatric and adult age groups.

Efforts have been initiated to address this for more diseases, through instigating closer collaboration between pediatric and adult clinics/hospitals.

- None of the Greek CoE's adhere to all the standards defined by the Council Recommendations; mainly they fail in aspects of research, teaching and education, dissemination of information and collaboration with patient organizations. It must be acknowledged that some of them do provide high quality patient healthcare.

4.4 Access to information

- **Not addressed by current Greek DEPARTMENTS/CLINICS for RDs**
- There is currently no National register for CoEs but an initiative to create one has been initiated by KEELPNO.

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

Not addressed by current Greek DEPARTMENTS/CLINICS for RDs

4.6 Good practice guidelines

Not addressed by current Greek DEPARTMENTS/CLINICS for RDs

4.7 Diagnostic and genetic testing

This was discussed under Greek WGI (Chair: G. Voutsinas, PhD & Raporteur C. Manolakakis)
Active participants included

- E. Fryssira (Assoc Professor of Genetics, Athens University, Laboratory of Medical Genetics)
- M. Tzetis (Assist. Professor of Genetics, Athens University, Laboratory of Medical Genetics)
- M. Papdakis (Chair of the Greek Association of Medical Genetics)

ACTIONS	INDICATORS	TYPE	ANSWERS (Greece)
Ensure quality of RD diagnosis laboratory	Existence of a public directory/ies of both genetic tests on Rare Diseases	Process	**NO- current full directory except for those labs listed in Orphanet**
	Proportion of laboratories having at least one diagnostic test validated by an external quality control	Outcomes	**NONE UNDER THE NATIONAL HEALTH SYSTEM, ALTHOUGH SOME LABS PARTICIPATE IN EQA SCHEMES (SOME LABS WITHIN THE PRIVATE SECTOR HAVE ACCREDITATION)**

KEELPNO and ORPHANET have each initiated some actions to identify all public hospital laboratories providing genetic tests in order to define the numbers of laboratories and also for which RD genetic tests exist in Greece.

The participants also described the approaches currently applied in genetics laboratories in the Greek Health System for diagnosis of RD patients with genetic diseases. The strategies and

methodologies applied are in accordance to practices world-wide, including full clinical evaluation, application of a wide range of validated genetic tests and supportive counseling for

patients and their families. However, there is no clear support from the Greek Ministry of Health for staffing these laboratories, nor are the clinical and laboratory specializations related to genetics recognized in Greece.

It was proposed that it should be the role of the MINISTRY OF HEALTH to support all laboratories already providing genetic tests to achieve Accreditation (ISO 15189) and participate in annual External Quality Assessment schemes run by e.g. NEQAS, EMQN, Eurogentest etc.
Furthermore there is currently no comprehensive national policy for costing and charging genetic tests for RD patients. There have been several initiatives to establish costs for RD genetic tests, with the aim of including them within the cover offered by the public health insurance schemes.

4.8 Screening policies

ACTIONS	INDICATORS	TYPE	ANSWERS (Greece)
Develop Screening Policies	Number of diseases included in the neonatal screening programme	Outcomes	**Number of diseases = FOUR UNDER THE AUSPICES OF THE NATIONAL HEALTH SYSTEM = PKU, G6PD, HYPOTHYROIDISM, GALACTOSEMIA,**
	Number of diseases included in the neonatal screening programme properly assessed	Outcomes	**NONE**

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

Not really addressed. There is some participation of some “CoEs” in European Reference Networks, meaning that these particular CoE’s collaborate with relevant international partners individually, without national collaboration.
There is no centralized or national register listing these centres, and thus no general awareness.

4.10 Sustainability of CoEs

Not addressed in the Greek EUROPLAN II meeting (considered not currently relevant)

Theme 4 General conclusions/suggestions

In the current absence of a structured Health System in Greece there are no Centres of Expertise or Centres of Excellence (CoE) that fulfill the EUCERD criteria to date. There are departments/clinics/teams that could be termed Centres of Reference for some diseases/disease groups but in the current absence of a centralized registry the access of RD patients to holistic health care pathways (from diagnosis and then all stages of healthcare and therapy, including, when necessary, transition from childhood through adulthood) is often fragmented and not guaranteed for all RDs.

For this reason, the Greek Europlan II Conference recommended that a practical step towards the ultimate, optimal healthcare pathways would be the establishment of interim "Centres of Coordination" for RD patient care, as predecessors of CoE's. These centres would have an initial role to co-ordinate the existing RD healthcare infrastructure throughout Greece (supported by information provided by the current activities of KEELPNO, ORPHANET and PESPA – see above) to support a network of all activities required for COMPLETE healthcare pathways of patients with RD. The coordination will also include the clinical diagnostic procedures and long-term patient follow-up.

With respect to access of RD patients to diagnosis, especially laboratory and genetic diagnosis, it was proposed that the MINISTRY OF HEALTH support all laboratories already providing genetic tests to achieve Accreditation (ISO 15189) and to participate in annual External Quality Assessment schemes run by acknowledged bodies. Furthermore a comprehensive national policy for costing and charging genetic tests for RD patients should be created, with the aim of including them within the cover offered by the public health insurance schemes.

Theme 5 – Orphan Medicinal Products (Greek Europlan Conference WGI: Access of Patients with Rare Diseases to Diagnosis and Medical Care

(see also Theme 4.7 reported above)

Stakeholder participants: I. Tountas, K. Frouzis, N. Karapanos, A. Kypreos.
Chairs and Rapporteurs: G. Voutsinas, C. Manolakakis

Dr. Makis Voutsinas PhD
Present at the Workshop with active participation were:

- M. Skouroliakou (Deputy Chair of the Greek Organization for Medical Products - EOF)
- K. Frouzis (Chair of the Association of Greek Pharmaceutical Companies –SFEE)
- E. Gavriil (Head of The Institute of Pharmaceutical Research and Technology – IFET)
- N. Karapanos (Ministry of Health)

Sub-Themes:

5.1 Support to Orphan Drug (OD) development
This was not discussed at in depth during the Greek Europlan II meeting, but it was agreed that all ODs should be available in Greece, including new drugs, as and when they become available.

5.2 Access to treatments
5.3 Compassionate use programmes
5.4 Off label use of medicinal products
5.5 Pharmacovigilance

Most aspects of the above topics (5.2-5.5) were discussed in general by the following speakers:

Mrs. Skouroliakou (EOF) spoke on the following topics:

- Pricing by priority
- Pricing policy (mainly of new medicines)
- Recording deficiencies
- Palliative treatment and early access palliative treatment
- Sorting by disease and drug

Comment by Mr. Manolakakis:

- He brought up the topic on shortages of some medicinal products, although EOF (Greek Organization for Medical Products)claims that the problem is being monitored.

Reply by Mrs. Skouroliakou:

- Parallel exports are prohibited by EOF (But they do happen. Author's comment).

Audience:

- Proposal for the creation of a committee for orphan drugs.

Reply by Mrs. Skouroliakou:

- This has been frozen temporarily, but there is a positive approach to the proposal.

Mr. Frouzis spoke on the following topics:

He proposed that all medicines be available within Greece. Whenever a new medicine is marketed it should also be immediately able to be imported to Greece.

He raised the issue of reimbursement for supplementary drugs, since the burden on patients is soaring.

- Last year expenses on medicinal products in Greece reached 2.9 billion €, while in 2013 it is not expected to exceed 2.45 billion €.
- He made the following suggestions:
- He disagrees with the new criteria of the medicinal product list in Greece.
- He strongly disagrees with the new policies for the contribution rates by patients when receiving medicinal products.
- The policy on the "strength" of the active substance in medicinal products should not apply in 2013-2014, so as not to cause confusion to the doctors, pharmacists and patients.
- Access to new treatments in Greece is expected imminently with the introduction of 7 to 10 orphan drugs not currently available.
- He proposed that pricing should be according to a "common sense" business model. Currently the price of each medicinal product in Greece is calculated as the average of the 3 lowest prices for that drug in all EU Member States. It would be more logical and functional if the price was calculated at 7-8% surcharge of the average of the price in all EU Member States.
- With reference to the issue of pricing, he suggested that there should be incentives for companies to come to Greece to support the development phase of medicinal products.
- The benefit from cheap generic drugs is not only an issue of economics but also affects e.g. clinical trials. This is probably due to cost-benefit economics. If pharmaceutical companies collaborate with the local branches to organize clinical trials, that'll be extremely beneficial for all of us.
- Policies should aim to reduce the burden on the wider social system in cases when there is no access to medicines. Based on the recently introduced system of "electronic prescriptions", the cost of medicinal products in Greece with 100% reimbursement is €60 million. **During the time when patients had no access to 100% reimbursement, overall health expenditure jumped to €600 million, due to the increase in need for hospitalization caused by reduced or no access to the essential medicinal products**.(When there is a problem of access to medicines then there is an increase in hospital costs by up to 30%).

Mr Frouzis made the following suggestions:

* Cooperation between patients and other stakeholders.

* Proposal for the enactment of a committee for RD. (A RD committee has been created in the Ministry of Health. *Author's Note*)
* Changes in the structure of the system (which is the main problem).

Mr. Manolakakis commented:
If pharmaceutical companies are discouraged from investing in Greece, it will not only have a negative impact on the economy (eg. jobs etc) but also severely restrict access of RD patients to the necessary range of medicinal products.
Mr. Frouzis commented:
In Greece the pharmaceutical industry has not been paid since 2006 (by the Greek health system, including hospitals and public health insurance schemes) but continues to function here.
So far withdrawal of medicinal products is minimal and overall patients are burdened by shortages rather than complete withdrawal of medicinal products.
Not only should parallel exports be banned, but there should be a better policy for pricing medicinal products.

Mrs. E. Gavriil spoke on the following topics:

- Currently 70 orphan medicinal products (OMP) are imported for various indications.
- The 43 have a price, 13 do not, 4 are new.
- 60% of orphan drugs are first imported through IFET (Institute of Pharmaceutical Research and Technology) and currently 35% of orphan drugs are imported by IFET.
- Many patients have access to medicinal products through IFET, and as long as a doctor will prescribe a medicinal product then a patient will have access to it. However, access to medicinal products in this way relates to an only small number of patients, and is not the norm. 63% of access to medical products occurs via hospitals and National Organization for Health Care (EOPYY), which both have financial difficulties.
- Access via IFET ensures timely coverage and the lowest possible price.

Mrs. Gavril made the following suggestions:

- Change the payment method of EOPYY to hospitals.
- Inclusion of all medicines within the Electronic Government Social Insurance (IDIKA) for "electronic prescription".
- Simplify the process of payments to pharmaceutical companies, for example by reducing the bureaucratic pathways through hospitals and their boards and by approving all patients' access to all medicinal products through EOF and minimal/no reimbursement through the public health insurance schemes
- Apart from orphan medicinal products (OMP) other medicinal products are consumed, related to the disease.
- Some of the delay or total lack of access to medicines for patients may in part be attributed to the refusal or reservation of physicians to prescribe.

Mr. N. Karapanos spoke on the following topics:

- He commented that a stable institutional framework does not exist:
  - That patients do have problem accessing medicinal products.
  - That there are problem with pricing medicinal products.
- That a committee to address and resolve issues such as the pricing of medicinal products does not exist.
- Specific medicinal products (such as for metabolic diseases) should be included and compensated in order for patients to have access.
- Question from audience:
- Is there a timetable to carry out your proposals;

Nick Karapanos:
There is a trend towards a positive approach however there is currently no timetable.

Area to be explored	Aims	Actions	Indicators	Type of indicator	Answers (Greece)
Gathering the expertise on Rare Diseases at European level	To ensure and accelerate accessibility to Orphan Designated Drugs (ODD)	Ensure the mechanism that facilitates ODD access and the reimbursementof their cost to patients after they got the market authorization by EMEA	Number of ODD market authorizations by EMEA and placed in the market in the country	Outcome	**Index based on Number of ODD placed in the market by total of ODD approved by the EMEA**
			Time between the date of a ODD market authorization by EMEA and its actual date of placement in the market for the country	Outcome	**It should be up to 90 days but to date over 28 months have passed and the matter is still pending.**
			Time from the placement in the market in the country to the positive decision for reimbursement by public funds	Outcome	**After positive price list 60 to 90 days**
			Number of ODD reimbursed 100%	Outcome	**Law 3816, Depending on strength of ODD (OMPs have been graded according to "strength"**
		To develop mechanisms to accelerate ODD availability	Existence of a governmental program for compassionate use for Rare Diseases	Outcome	• **No** • **In process**

Theme 5 General conclusions/suggestions

The general policy of the government is to cut the bill for healthcare overall. With respect to medicinal products, instead of evaluating the in depth cost-effectiveness of each drug currently available in Greece, they are making cuts across the board which often has counter-productive effects by in fact increasing healthcare costs due to negative health outcomes of patients deprived of correct and necessary medicines. Furthermore they are not permitting any changes to the lists of medicinal products authorized in Greece i.e. no new medicinal products or OMPs are being licensed, which again may be a counterproductive measure, since some new medicinal products may offer a more economical benefit to patients and thus the healthcare system in the long-term.

Post-conference's note: As of 25 July 2013, these drugs have received pricing thanks to PESPA's efforts.

The general proposal by all stakeholders and RD patients present in this WG was to change the structure of the current system through the creation of a stable institutional framework, sensible pricing and reimbursement policies for medicinal products as well as supplementary medicinal products. With particular emphasis on the access of RD patients to medicinal products, these aims should be supported by the activities of a specific committee for RD under the Ministry of Health and the collaboration between patients and other stakeholders. In conclusion there is a urgent need for a committee to address and resolve issues such as the pricing of medicinal products and reimbursement.

Theme 6 – Specialised Social Services for Rare Diseases

(Greek Europlan Conference WGII)

Sub-Themes

Stakeholder participants: C. Nastas, K. Souliotis, S. Tsaroucha
Chairs and Rapporteurs: V. Biliou, G. Makris
Present at the workshop with active participation were:

- Mrs V. Biliou, President of the Greek PWS Organisation
- Mr G. Makris, President of the Greek Association for Myopathies
- Dr K.Souliotis, Assistant Professor of Health Policy, Faculty of Social Sciences, University of Peloponnese
- Mr C. Nastas. Secretary General of the National Confederation of Disabled People (N.C.D.P.)
- Mrs S. Tsaroucha, Registered Nurse, Palliative Care at Home Service of "Merimna"
- Members of patients associations as well patients or relatives and students.

The workshop was attended by numerous members of patients associations, patients or relatives and students.

6.1. Specialised social services for rare diseases

6.2. Policies to integrate people living with rare disease into their daily life

EUROPLAN INDICATORS ON PATIENT EMPOWERMENT

ACTIONS	INDICATORS	TYPE	ANSWERS (GREECE)
Compensating disabilities caused by rare diseases	Existence of official programs supporting patients and families with disabilities	Process	**Not exclusively for RD**
	Existence of an official directory of social resources for patients with disabilities	Process	**Yes, but not specialised on RD**
ACTIONS	**INDICATORS**	**TYPE**	**ANSWERS (GREECE)**
Supporting Rehabilitation programmes for RD patients	Existence of programmes to support rehabilitation of RD patients.	Process	**Yes, and they include financial support, however not specialised for RD**
ACTIONS	INDICATORS	TYPE	ANSWERS (GREECE)
Supporting social services aimed at rare disease patients and their families. disease patients and their families.	Existence of national schemes promoting access of RD patients and their families to Respite Care Services	Process	**No**
	Existence of public schemes supporting Therapeutic Recreational Programmes	Process	**No**
	Existence of programmes to support integration of RD patients in their daily lives	Process	**No**

6.3. Social resources for people with disabilities

There are no national policies to support social resources for RD patients in Greece.

6.4. Specialised social services for rare diseases

Noted the almost complete absence of Rare Diseases from the Disability Severity Assessment (KEVA) and, thereby causing dysfunction in the correct and proper (delays, unnecessary reviews, rates of unnecessary suspensions, incompetence committees etc) evaluation of the

respective patients from Disability Certification Centers (KEPA), and the need for manning the latter with the specificity of geneticists.

6.5. Policies to integrate people living with rare disease into their daily life

The policies that exist are poorly structured and do not function to easily support integration of people living with a RD (or their families) into daily life.

Theme 6 General conclusions/suggestions

In the light of the severe inadequacies identified through discussion in this WG, several suggestions were made, including:

• To reorganize the structure and protocols followed when evaluating RD patients and their level of disability from the current system under the National Organization of Health Services (EOPPY) which designates committees of physicians who are often completely unfamiliar with the disease-specialization of the patient under evaluation, by recommending the make-up of committees with relevant specializations by widening the available pool of medical specialties.

• To make it mandatory that all physicians describe all diseases with the relevant ICD-10 code. This would record and generate more measurable data for all RDs in Greece, as well as supporting the transition of codification to the ICD-11 classification.

• That all Medical Bodies as well as the Central Board of Health (KESY) should contribute to the process of Disability Severity Assessment (KEVA) and Disability Certification Centers (KEPA).

• To widen the specialization of the personnel on the committees of the Disability Certification Centers so that, in addition to evaluating the level of “disability' of the RD patient, they can also assess whether the RD patients has the capability to work and to what degree; currently this is done by medical personnel only, who are not informed about the details of disability compensation and rehabilitation programmes etc..

With respect to other In Social Benefits and Services it was highlighted during the meeting that there is a lack of awareness and expertise in Rare Diseases in all existing structures, including early intervention, rehabilitation, integration in the education system, home care, assisted living accommodation and finally leisure facilities. In fact currently the majority of support that does exist for RD patients in Greece is through NGOs (Such as PESPA), private organizations and other social bodies which address the needs of RD patients symptomatically and sporadically.

For this reason, further suggestions included:

•The establishment of National Centres for Palliative Care and Supported Employment.
•The organization of all existing structures in a single network.

The meeting emphasized the urgent need for a strong movement towards patient empowerment to demand these rights and for insuring funding for legal actions against a discriminating government.

In conclusion and even though small steps towards improvement, since the previous Europlan meeting, have been taken (establishment of a Rare Diseases Committee in the Ministry of

Health and Welfare, unification of pension/welfare payment committees) there are a lot to be done in every aspect of Social life in terms of Benefits and Services in Rare Diseases.

6.6. International –supranational dimension

This was not discussed at the Greek Europlan II meeting.

Horizontal Themes

The "Horizontal Themes" including "Sustainability", "Patient Empowerment" and "Gathering Expertise on Rare Diseases at the EU level" were addressed within the various WGs in the Greek Europlan II meeting, especially the issue of "Patient Empowerment", which was also emphasized by the high numbers and active participation of RD patients.

Patient Empowerment

ACTIONS	INDICATORS	TYPE	ANSWERS (GREECE)
Promoting the existence of a RD patients' organisation that represents all RD patients' associations	Number of umbrella organisations specific on rare diseases	Process	**Only one umbrella organisation exists (PESPA)**
	Having a directory of RD Patients' organisations	Process	**Yes. listed with all other associations by the Ministry of Health**
	Number of RD patients' associations	Outcomes	**There are at least 30 associations, 25 of which are members of PESPA**
	Number of diseases covered by patients' associations	Outcomes	**Based on the registry of PESPA there are at least 180 RDs in Greece**
ACTIONS	**INDICATORS**	**TYPE**	**ANSWERS (GREECE)**
Patients' Organizations involvement in decisions affecting RD	Permanent and official patients' representatives in plan development, monitoring and assessment	Process	**Representation has not been yet clearly defined, but the Secretary General of the Ministry of Health has committed verbally to establish institutional representation in all RD areas.**
	Participation of patients' organisations in the development of RD research strategies	Process	**No**

ACTIONS	INDICATORS	TYPE	ANSWERS (GREECE)
Support the activities performed by including patient organisations, such as : • Awareness raising • Capacity building and training • Exchange of information and best practices • Networking • Outreach very isolated patients	Resource (funding) provided for supporting the activities performed by patient organisations	Outcomes	**Does not exist**
	Support to sustainable activities to empower patients, as stated before	Outcomes	**Not even a plan exists**
ACTIONS	INDICATORS	TYPE	ANSWERS (GREECE)
Building – supporting the existence of comprehensive help line for patients	Availability of Help Line for RD patients	Process	**No formal decisions have been taken**

Conclusion of the Final Report

The information in this report was based on the situation up to 1st December 2012 when the Greek Europlan II Conference was held. It must be noted that the financial crisis in Greece, is continuing to progressively undermine many aspects of the public sector, including healthcare, and since December 2012 there have already been some changes with respect to certain financial and legal aspects relating to healthcare, hospitalization, medicinal products etc. Below are summarized the conclusions of the Greek Europlan II report.

Theme 1 was not addressed during the Greek Europlan II conference since the Greek State has made no progress in initiating the application of the Greek National Plan, which has remained on paper only.

Under **Theme 2 and 3.6** the following were concluded:

- Official lists of RD do not exist in Greece. However there are four different kind of registries that could be useful: 1. Those based on the unique identification number (AMKA) of every Greek citizen, a strategy recently adopted by the National Health and Welfare System 2. Registries created by patient organizations, for example the one created by the Greek Alliance for Rare Diseases (PESPA) 3. Registries of academic researchers and medical doctors, and, 4. Registries of pharmaceutical companies.
- Due to the current fragmentation of RD registries in Greece, the creation of a Registry of Registries is deemed very important, and the most practical approach. The collaboration of all stakeholders will be critical in order to improve the quality of registries and insure a viability of all existing registries.

Theme 3 was not addressed during the Greek Europlan II conference since there has been no progress on the side of the Greek State to support funding for research on RD in Greece (no policies, no dedicated RD research programmes, no priorities for research in the field of RDs, no fostering of interest and participation of national laboratories and researchers, no RD research infrastructures and registries). Any EU and international collaboration on research into RD is sporadic and based on the initiative of individual research groups. Only a couple of research projects on RD have been funded through the e-Rare programme in the past.

Theme 4 included the following general conclusions and suggestions:

- In the current absence of a structured Health System in Greece, there are no Centres of Expertise or Centres of Excellence (CoE) that fulfill the EUCERD criteria to date. There are departments/clinics/teams that could be termed Centres of Reference for some diseases/disease groups but in the current absence of a centralized registry, the access of RD patients to holistic health care pathways (from diagnosis and then all stages of healthcare and therapy, including when necessary transition from childhood through adulthood) is often fragmented and not guaranteed for all RDs. Those Centres of Reference that do exist are self-defined as such and have not undergone any external quality assessment.

- For this reason the Greek Europlan II Conference recommended that a practical step towards the ultimate optimal healthcare pathways would be the establishment of interim "Centres of Coordination" for RD patient care, as predecessors of CoE. These centres would have an initial role to co-ordinate the existing RD healthcare infrastructure throughout Greece (supported by information provided by the current activities of KEELPNO and ORPHANET) to support a network of all activities required for COMPLETE healthcare pathways of patients with RD. The coordination would also include the clinical diagnostic procedures and long-term patient follow-up.
- With respect to access of RD patients to diagnosis, especially laboratory and genetic diagnosis it was proposed that it should be the role of the MINISTRY OF HEALTH to support all laboratories already providing genetic tests to achieve Accreditation (ISO 15189) and participate in annual External Quality Assessment schemes run by recognized European bodies e.g. NEQAS, EMQN, Eurogentest etc.
- There is currently no comprehensive national policy for costing and charging genetic tests for RD patients. There have been several initiatives to establish costs for RD genetic tests, with the aim of including them within the cover offered by the public health insurance schemes. This issue is yet to be conclusively addressed in Greece.

Theme 5 included the following general conclusions/suggestions:

- The general policy of the government is to cut the bill for healthcare overall. With respect to medicinal products, instead of evaluating the in depth cost-effectiveness of each drug currently available in Greece, they are making cuts across the board which often has counter-productive effects. In many cases in fact healthcare costs are increasing due to negative health outcomes of patients deprived of correct and necessary medicines. Furthermore in Greece no new orphan medicinal products (OMPs) are being licensed, which again may be a counterproductive measure since some new medicinal products may offer a more economical benefit to patients and thus the healthcare system in the long-term.
- The general proposal by all stakeholders and RD patients present in this WG at the Greek Europlan II conference was to change the structure of the current system through the creation of a stable institutional framework, sensible pricing and reimbursement policies for medicinal products as well as supplementary medicinal products. With particular emphasis on the access of RD patients to medicinal products, these aims should be supported by the activities of a specific committee for RD under the Ministry of Health and the collaboration between patients and other stakeholders. In conclusion there is an urgent need for a committee to address and resolve issues such as the pricing of medicinal products and reimbursement.

Theme 6 included the following general conclusions/suggestions:

- Discussion in this WG at the Greek Europlan II conference highlighted severe inadequacies.
- There is an urgent need to reorganize the structure and protocols followed when evaluating RD patients and their level of disability from the current system under the National Organization of Health Services (EOPPY) which designates committees of

physicians who are often completely unfamiliar with the disease-specialization of the patient under evaluation, by recommending the make-up of committees with relevant specializations by widening the available pool of medical specialties.

- It should be made mandatory that all physicians describe all diseases with the relevant ICD-10 code. This would record and generate more measurable data for all RDs in Greece, as well as supporting the transition of codification to the ICD-11 classification.
- All Medical Bodies as well as the Central Board of Health (KESY) should contribute to the evaluation process of Disability Severity Assessment (KEVA) and Disability Certification Centers (KEPA).
- The specialization of the personnel on the committees of the Disability Certification Centers should be broadened so that, in addition to evaluating the level of “disability' of the RD patient, they can also assess which RD patients have the capability to work and to what degree. Currently this now is done by medical personnel only, who are not informed about the details of disability compensation and rehabilitation programmes etc..
- With respect to other Social Benefits and Services it was highlighted during the meeting that there is a lack of awareness and expertise in Rare Diseases in all existing structures, including early intervention, rehabilitation, integration in the education system, home care, assisted living accommodation and finally leisure facilities. In fact currently the majority of support that does exist for RD patients in Greece is through NGOs, private organizations and other social bodies which address the needs of RD patients symptomatically and sporadically.

For this reason, further suggestions included:

- The establishment of National Centres for Palliative Care and Supported Employment
- The organization of all existing structures in a single network.
- The meeting emphasized the urgent need for a strong movement towards patient empowerment to demand these rights and for insuring funding for legal actions against a discriminating government.

Generally Theme 6 concluded that even though small improvements have been made since the previous Europlan meeting in 2010, (for example the creation of a RD committee under the Ministry of Health, or the joining of committees for evaluating benefits and pensions) there is still a lot to be done in every aspect of Social life in terms of Benefits and Services for Rare Disease patients.

Overall the Greek Europlan II Conference found the European guidelines and policy Recommendations (including EUROPLAN Recommendations, EUROPLAN Indicators for the advancement of a national strategy in the country, EUCERD Recommendations) theoretically useful as a framework to support the creation of goals towards which Greece should strive to achieve optimum health and social care for all RD patients. However, with the severe absence of political will and correctly functioning institutions in Greece, it is probably going to be extremely difficult to transfer most aspects of the guidelines and policy recommendations to Greece. The Greek RD patients, their friends and some sympathetic stakeholders, under the

dynamic umbrella of PESPA, will continue campaigning to promote the implementation of the Greek National Plan. The on-going interaction with and support from EURORDIS is of fundamental importance to help bring about the improvements needed for the optimum benefit of RD patients.

Annexe I - Final Programme of the National Conference

EUROPLAN II
December 1st 2012
Eugenides Foundation

09:00 – 10:00 **Registration – Coffee**
10:00 – 10:15 **Welcome – Conference Start – Speech by Simona Bellagambi(?)**
10:15 – 10:45 **Speech by Antoni Monsterrat Moliner**
10:45 – 11:30 **Review of EUROPLAN I –**
Introduction to EUROPLAN II
Presented by EUROPLAN Advisor, Simona Bellagambi
11:30 – 12:00 **Coffee Break**
12:00 – 14:00 **Workshops**

The Access of Patients with Rare Diseases to Diagnosis and Medical Care

Representatives of Stakeholders : A. Athanasiadou, K. Frouzis, E. Frysira, N. Karapanos, A. Kypreos, N. Kollias, C. Lionis, E. Michelakaki, M. Papadakis, Th. Stavrou, I. Tountas, M. Tzeti,
Coordinators: G. Voutsinas, C. Manolakakis

A) Diagnosis

a) Clinical Diagnosis
b) Laboratory Diagnosis and its Framework

B) Treatment

a) Access to treatment
b) Orphan Drugs: availability, approval, pricing and patient participation
c) Palliative care oddities regarding off-label drugs
d) Common and Generic Drugs: availability, approval, patient participation, safety
e) Special products and expendables

Social Care for Patients with Rare Diseases

Representatives of Stakeholders: Representative of the Ministry of Labour, C. Nastas, K. Souliotis , S. Tsaroucha
Coordinators: V. Billiou, G. Makris

a) Determination of the Level of Disability
    - Omitted Rare Diseases

- The presence of Geneticists in the Formatting Process

Centers of Disability Certification

- Frequency of the Evaluation of Patients
- Complement and Responsibilities of the Committees
- Waiting Period

b) The participation of patients or their representatives in the decision-making process

c) Palliative care

Rare Diseases Reference Centers

Representatives of Stakeholders: J. Traeger –Synodinou, S. Youroukos, E.S. Doudounakis, E. Papadopoulou – Alataki

Coordinators: D. Synodinos, A. Gliati

a) Improving the current, and developing new, Reference Centers*

b) Transition from childhood to adulthood care

c) Establishing cross-border healthcare in Reference Centers for Rare Diseases

*Collaboration of doctors of different specialties for diseases affecting multiple systems

Rare Diseases Registries in Greece

Representatives of Stakeholders: E. Kanavakis, V. Sfyroeras, D. Yannoukakos, Y. Koutsostathis

Coordinators: M. Lambrou, E. Floka

a) National Rare Diseases Registries

- National - Government based
- Patients associations registries
- Academic - Research oriented
- Pharma Industry registries

b) Utilizing the data of the registry

14:00 – 15:00 **Lunch Break**

15:00 – 16:30 **Continuation of the Workshops**

16:30 – 17:00 **Coffee Break**

17:00 – 18:00 **Conclusions from the Workshops**

18:00 – 18:30 **Discussion and Closing the Conference**

Annexe II – Press Release

PRESS RELEASE

The EUROPLAN II Conference organized by the Greek Alliance for Rare Diseases was met with great success

The EUROPLAN II Conference organized by the Greek Alliance for Rare Diseases, that took place in the Eugenides Foundation on December 1st 2012**,** was met with great success, with the acceptance and active participation of all the involved stakeholders, as well as an impressive attendance by patients from all over the country.

The goal of the EUROPLAN II program is the creation and implementation, by all European countries, of a basic plan of action for rare diseases, which are approximately 6.000-8.000, from which, based on statistical data, more than 36 million people (and their relatives) in Europe – 1 million of which are in Greece- are afflicted.

This program is coordinated by the European Organization for Rare Diseases (**EURORDIS**) and the patient association responsible for organizing the conference in Greece is the **Greek Alliance for Rare Diseases.**

The Conference was held under the auspices of His Excellency, the President of the Hellenic Republic, mr. Karolos Papoulias.

The Greek Alliance for Rare Diseases was honored by the presence of Mr. Antoni Montserrat Moliner, Policy Officer for Rare and Neurodevelopmental Diseases, Health and Consumers General – Directorate, who addressed the attendees during the salutations of the Conference.

During the Conference, four working groups were created, in which various stakeholders from EOF, IFET, SFEE, as well as patients participated, and that worked on subjects that were predetermined by the EUROPLAN program:

1. Patients' Access to their Diagnosis and Medical/Pharmaceutical Care
2. Social Security Rights for Patients with Rare Diseases
3. Reference Centers for Rare Diseases
4. Rare Diseases Registries in Greece

The results of the working groups are focused on present-day problems for Greek patients with rare diseases, changes that need to be made, as well as new suggestions, in that way shaping a complete plan of action for rare diseases, which will form the basis of the final report that will be sent from Greece to the European Parliament.

For example, some of the actions suggested during the conference, and will be implemented in the official report, are the following:

- Establishment of already existing clinics as Reference Centers for Rare Diseases and creation of new ones (i.e. Children's Hospital, Sismanoglio, Evangelismos)
- The Participation of patients in the decision-making process for subjects that have to do with their medical/pharmaceutical care.
- Establishment of the mandatory use of the ICD10 codification for rare diseases in the electronic prescription process, so that fully measurable data can gathered for every disease.
- Cooperation of all registry stakeholders in Greece, for the creation of a common network.

All final reports of the remaining member states, which will be sent to the European Parliament, will be analyzed thoroughly, with the goal of selecting the appropriate elements to be implemented in the common policy for all European countries.