

# **Minutes**

## **6th Meeting of the European Commission “Rare Disease Task Force” Luxembourg, 14 December 2006**

On 14 December 2006, the sixth meeting of the Rare Diseases Task Force (RDTF) included the attendance of:

### **Rare Disease Task Force:**

V. Anastasiadou	E. Jessop	D. Taruscio
S. Aymé	Y. Kodra	A. Trama
S. Berrih-Aknin	C. Nourissier	M. Vihinen
K. Beuzard-Edwards	M. Posada de le Paz	J.L.Vives Corrons
J. Donadiou	A. Ramirez Vanegas	C. Webb
L. Fregonese	C. Malattia	S. Webb
G. Gatta	J. Sandor	
N. Kerlero de Rosbo	R. Stefanov	

### **Observers:**

R. Capocaccia  
A. Federico  
S. Giampaoli  
A. Phinikaridou  
M. Ratsep  
M. Carl  
F. Kendel

### **European Commission:**

C. Berens  
G. Margetidis  
A. Montserrat  
J. Ryan  
J. Waligora

## **A. Welcome and Approval of Agenda**

No changes.

## **B. Presentation on the Disseminations of the European Community Health Indicators**

Antoni Monserrat  
European Commission  
DG SANCO Health Information Unit

### **Current Work Plan**

The DG SANCO's Health Information Unit aims to produce an EU health information system with indicators on health-related behaviour, diseases, and health systems. The information system is being developed on the basis of several Public Health Programme (2003-2008) projects and other EU actions, in collaboration with Eurostat, the OECD and the WHO. It is available through the DG SANCO website and the internet-based EU Health Portal.

One such Public Health Programme project contributing to the health information system is the European Community Health Indicators (ECHI) project carried out in the framework of the previous Health Monitoring Programme (1997-2002) and the current Public Health Programme. The objectives of this project:

- measuring health status, its determinants, and trends within EU,
- simplifying planning, monitoring and evaluation of EC Programmes and actions,
- providing Member States (MS) with relevant health information for national health policy-making,

result in a list of “indicators” for the public health field arranged according to a conceptual view on health and health determinants.

The current Work Plans 2005, 2006, 2007 contain explicit mention to chronic, major and rare disease (RD) indicators, thus constituting the legal basis for the development of an EU health information system:

- pilot studies on health examination surveys as part of the feasibility study
- creation or improvement of morbidity registers covering all MS on all major and chronic diseases for which a solid indicators base definition exists and for those not yet covered by existing projects
- provision of evidence & reports on community policies on health, health and economic growth, and sustainable development
- support for disease knowledge projects relating to prevalence, treatments, risk factors, risk reduction strategies, cost of illness, and social support
- development of strategies and mechanisms for exchange of information among people affected by RD and promotion of better epidemiological studies, coding, classification, and definition
- support for European networks of Centres of Reference (CR) for RD to define guidelines for best practice in treatment, and knowledge sharing on these diseases, along with performance evaluation
- feasibility studies to develop mechanisms for data collection on the volume and impact of cross-border healthcare, integrated into existing data collection systems within MS avoiding undue additional administrative burden

### **Seventh Framework Programme (FP7)**

The future legal basis for health indicator developments in EU Public Health Policy was presented:

In the 2007-2013 period a new Health & Consumer Protection Programme is expected to replace the existing Public Health Programme (pending Council and Parliament approval). A new strand, “Generation of Knowledge” will be introduced, but there will be no “Diseases” strand.

The Draft Regulation from the Council and Parliament (developed by Eurostat) is creating a statistical framework for data collection on health and safety in the workplace in some areas and should be an “umbrella regulation” to be developed via Commission Regulations.

A direct contract agreement via Commission Decision with OECD has been signed for developments in several areas.

A. Montserrat announced the Commission must now make some clear action in the RD field. There has been a suggestion to expand the existing 3 strands to 6 in the future Public Health Programme. The proposal was not accepted. Contribution to FP7 constitutes one of the Commission's priorities on RD.

A. Montserrat explained a new common approach between research activities and health information under the "Cooperation" specific programme of FP7. Emphasis will be put on translational research (translation of basic discoveries in to clinical applications), the development and validation of new therapies, methods for health promotion and disease prevention, diagnostic tools and technologies, as well as sustainable and efficient health care systems. For rare diseases specifically, the focus will be on pan-European studies of natural history, pathophysiology, and the development of preventative, diagnostic and therapeutic interventions. This sector will include rare Mendelian phenotypes of common diseases.

Under the "Ideas" specific programme of FP7, an entirely new approach will be taken. Unlike the approach under FP6 which does not fund activities that can be better conducted at a national or regional level, but focuses on topics of European or global significance, and supports projects involving cooperation between partners from several different European countries, the new approach will be an "investigator-driven" one, allowing researchers to propose their own topics. Grants will be provided for individual teams, allowing teams to be composed of any group of researchers required for the projects to achieve scientific excellence, rather than of members determined by administrative requirements.

### **2007-2008: Proposal for a Commission Communication on the European Health Information and Knowledge System**

Over 2007/2008 DG SANCO is to elaborate a proposal for a Commission Communication on the European Health Information and Knowledge System. This proposal includes:

- a summary of the principles of the EU Health Information and Knowledge System
- the responsibilities of different actors in the field of RD as well as the role of DG SANCO
- the national and EU responsibilities in the mechanisms for collecting health data
- the interoperability of different systems of health indicators and cooperation with other players such as Eurostat, ECDC, and OECD.
- the role of the consultative structures
- a code of good practices on health information
- the obligation of the European Commission to respect the individual decisions of MS in the field of health information.

This proposal should be discussed in all the existing DG SANCO advisory structures.

### **A Council Recommendation**

It is hoped that this Communication will be followed by a Recommendation from the Council. A. Montserrat stipulated that these Recommendations are the only legislative tool provided for by Article 152 on public health (except for certain measures or incentive measures may be adopted (see Article 152.4)). Between 2008 and 2011, new Communications, public

consultations or legal initiatives affecting health information issues, will be established. The consolidation of instruments to develop RD systems is considered very important.

A. Montserrat said it was important to remind members present of the significance of a Recommendation in the preparation of a Communication on RD. He pointed out that Recommendations do not have any legal status as such, but are negotiated and voted on according to the appropriate procedure. However, unlike Regulations, Directives and Decisions, Recommendations are not binding for MS. Despite their lack of legal impact, they do have a real political impact. So by definition, a Recommendation is an instrument of indirect action used in the preparation of legislation in MS, and differing from a Directive only by its absence of obligatory power. It is therefore appropriate and necessary to accompany the developing Communication with a Proposal for a Council Recommendation on RD.

A. Montserrat pointed out that the timetable for the elaboration of this Communication and Recommendation is already in the Annual Management Plan (AMP) 2007 in time to launch the Commission adoption by the end of 2007.

### **New Health Strategy**

In 2007 the Commission plans to adopt a new Health Strategy aiming to

- set a clear, strategic framework covering mainly DG SANCO work with some new initiatives,
- define broad objectives within a 10-year timeframe with a 5-year mid-term review
- encourage close cooperation with MS to improve health in Europe over coming decade,
- focus on key health issues, on mainstreaming health in all policies and address key challenges on global health issues.

RDTF members and all stakeholders are actively encouraged to submit their own input via comments on a discussion document on operational aspects of the Health Strategy by 12 February 2007. It is expected that this new strategy will be adopted mid to late 2007, after which it will be discussed by the Council.

### **Community Action on Health Services**

Before the Commission brings forward proposals for Community Action on Health Services, it consults all stakeholders involved in the health services sector, on the basis of a specific Consultation document. This Consultation is already in place (available on the DG SANCO website) and responses to this document should be sent to the Commission by 31 January 2007.

### **Improving Health Indicators**

To improve the mechanisms for health reporting common methodologies and systems of collection must be sustained and accepted by all the MS. To improve mechanisms of health reporting from a rare disease perspective the following actions are necessary:

- European Health Survey System (health interview survey (HIS) and health examination survey (HES) databases).

- revision of several international classifications. The European Commission is very involved in the revision process of the WHO ICD-10 with particular attention being paid to rare diseases.
- development of the System of Health Accounts
- a common system of collection of information on hospital activities
- development of some disease registers
- collection of information on primary care
- sentinel networks

### **Health Reports Based on Indicators**

The following series of significant Health Reports has been launched by DG SANCO as part of the 2006 Work Plan:

1 <sup>st</sup> Communicable Diseases Reports	3 <sup>rd</sup> Quarter, 2006	ECDC & SANCO C-2 & ESTAT
1 <sup>st</sup> Chronic Diseases Report	1 <sup>st</sup> Quarter, 2007	TF MCD
1 <sup>st</sup> Global Report on Health in EU	End 2008	EUGLOREH Project (Italy)
2 <sup>nd</sup> Report, European Conference on RDs	2008	RAPSODY Project (EURORDIS)

The 1<sup>st</sup> Global Report of Health in the EU will include a chapter on RD. A. Montserrat reminded members of the web address for the dissemination of indicators data, informing them that all MS languages will be available during 2007. The Report may be consulted at: [http://ec.europa.eu/health-eu/index\\_en.htm](http://ec.europa.eu/health-eu/index_en.htm).

### **Other DG SANCO Priorities on Rare Diseases**

#### Projects

With regard to the evaluation of project proposals, DG SANCO's priority criteria are: 1) projects that identify rare diseases and assess prevalence, 2) projects supporting cooperation between rare disease organisations, 3) projects creating networks of action for rare diseases. A. Montserrat reminded members of last year's successful project applicants, listing each of them.

#### European Conferences on Rare Diseases

- European Workshop on Centres of Reference for Rare Diseases (Prague, 12-13 July 2007)
- European Conference on Research on Rare Diseases (Brussels, 13 September 2007)
- European Conference on Rare Diseases (Lisbon, 27-28 November 2007)

#### Centres of Reference for Rare Diseases

DG SANCO has established the High Level Group (HLG) on Health Services and Medical Care as a means of taking forward the recommendations made by the reflexion process on patient mobility. One of the Working Groups of this HLG refers to reference networks of centres of reference

The RDTF Work Group on Centres of Reference (CR) has submitted a report “Contribution to policy shaping: For a European collaboration on health services and medical care in the field of rare diseases” updating the information about CR in Europe. The report details the use of the concept of CR in Europe as well as the respective functions. A. Montserrat summarised the suggested criteria to be fulfilled by a European reference network.

### The Orphan Regulation

A. Montserrat reminded members present of the importance of this Regulation (EC Regulation 141/2000) that was proposed to set up the criteria for orphan designation in the EU and describes the incentives (e.g. 10-year market exclusivity, protocol assistance, encouragement of R&D & marketing of RD medicines) to encourage research, development and marketing of medicines to treat, prevent, or diagnose rare diseases, thus better serving patients. The incentive programme has resulted in 32 new orphan medicines with marketing authorisations, more than 450 applications for orphan designation, and 270 medicines already designated as orphan medicinal products, but still undergoing clinical evaluation.

### **Discussion**

It was asked why so many projects were accepted by the Commission. With so many new projects accepted, existing ones experience 30-50% cut in funding while still having to meet the same objectives. Why not accept fewer outstanding projects with appropriate funding for each?

A. Montserrat explained that there was no official policy to reduce project budgets. There was competition between the projects involved and though this was not ideal, this was the system. He agreed that ideally the policy should be fewer projects and more funding for each.

It was asked why the evaluation of projects takes place in one week as it was felt that this time is too short. It was suggested that the Commission develop a 2-phase approach to the evaluation process with a pre-selection phase followed by a more in-depth evaluation.

A. Montserrat responded that unfortunately the current resources available to the Commission only allow for one week of evaluation.

Project budgeting was addressed as a real problem to researchers as the process has become more and more complicated. Several members identified with this struggle. Consultation with others, and sharing of budget experiences and abilities was encouraged.

It was suggested and agreed upon that a smaller working group be assembled to prepare the Communication content in time for the next RDTF meeting in June 2007, but that all members of the task force would continue discussing topics together. Task force members interested in contributing to this work group included: **J. Llinares-Garcia, C. Berens, E. Jessop, D.Taruscio, C. Nourissier, L. Fregonese, and J. Sandor.**

## **C. Presentation on Research on Rare Disease: Overview of FP6 activities**

Catherine Berens

European Commission

DG Research Health Directorate – Medical and Public Health Research Unit

## **Fifth Framework Programme and Sixth Framework Programme**

Under FP5 the RD budget was 64 million € which included 47 RD projects in research and development, infrastructure, and biotechnology.

Members were reminded that topics in FP6 relevant to RD were often found under other headings. To track current RD projects, members were encouraged to use the following website:

<http://cordis.europa.eu/lifescihealth>

→ Thematic Areas

→ Application-orientated genomic approaches to...

→ Combating cardiovascular disease, diabetes and rare diseases

→ FP6 rare disease projects

(<http://cordis.europa.eu/lifescihealth/major/rare-disease-projects1.htm>)

The global budget for RD under FP6 is ~230 million € with 59 projects selected for funding related to RD. Under Priority Thematic Area 1 of FP6 -Life Sciences, Genomics and Biotechnology for Health- there were four calls for proposals.

In addition to funding disease specific research projects, a transversal project was also funded, OrphanPlatform, aimed at developing a platform with information tools to address the set of factors that currently affect research on rare diseases and its coordination by (1) developing an information service, freely accessible on Internet, dedicated to research activities in the field of rare diseases and orphan medicinal products, including a database of research projects, funded at MS level and at the EU level, and a database of collections and research networks, (2) developing services aimed at speeding up the enrolment of patients in clinical research, (3) developing a database of research projects with development potential, to help scientists and Industry establish the necessary partnerships. This Platform is accessible at [www.orpha.net](http://www.orpha.net) and at [www.orphanxchange.org](http://www.orphanxchange.org).

C. Berens explained the need for dialogue between the scientific community and society at large. One such project, “Capacity-Building for Patient Organisations in Research Activities (CAPOIRA)” aims to equip rare disease patients and patient organisations with the knowledge necessary to take action in research activities and policy. The project is built along two main activities:

1) “Understanding clinical trial protocols”: six training sessions in 3 MS

2) ‘Gaining Access to Rare Disease Research Resources’: a two day European workshop in Paris, 4-5 May 2007, to increase the capacities of patient representatives to understand the concepts, vocabulary, policies, and instruments of health research activities at the EU level.

C. Berens continued by highlighting the achievements of the FP6 Programme:

- mobilisation of top researchers, tackling fragmentation, production of new knowledge
- coordination of the field at EU level (e.g. OrphaPlatform and E-Rare)
- mobilisation of and dialogue with stakeholders (including patients)

And room for improvement remains in the following areas:

- clinical research
- focused topics
- emerging consortia/topics

## **Seventh Framework Programme**

The first framework programme to run for seven years from 2007-2013, FP7 has a total budget of 50,521 million €. The “Cooperation” sector is the biggest at 32,413 million € of which Health takes up 6,050 million €. The “Cooperation” sector is comprised of ten themes of which Health is the first.

The Health objectives were outlined, covering improvement, global health issues and increasing competitiveness in related industries, and the rationales behind them were presented. Health is broken down into 3 “pillars”: 1) Biotechnology, generic tools & medical human health technologies; 2) Translating research for human health; 3) Optimising the delivery of healthcare to European citizens including better clinical practice and use of medicines, quality, efficiency & solidarity of health systems, and enhanced health promotion/disease prevention.

C. Berens then turned to Collaborative Research with explanations for the different funding schemes within the FP7:

- Small or medium-scale focused research actions (STREP)
- Large-scale Integrated Projects (IP)
- Networks of Excellence (NoE)
- Coordination actions (CA)
- Specific Support Actions (SSA)

An important scheme in funding is the continuation of Marie Curie Actions which include support for training and career development of researchers and are open to third country nationals.

C. Berens set out the principles of the FP7’s new European Research Council (ERC). She explained that the ERC will be the first pan-European funding agency for innovative projects. Investigators with a range of experience from across Europe will be able to compete for ERC grants with scientific excellence as the only criterion for funding. Funding will be distributed via two schemes: 1) ERC Starting Grant and 2) Call Advanced Grant

C. Berens introduced new support for existing and new research infrastructures of which 6 are relevant for health issues:

- EATRIS (European Advanced Translational Research Infrastructure in Medicine)
- European biobanking and biomolecular resources
- Mouse models for life sciences (INFRAFRONTIER)
- Infrastructures for clinical trials and biotherapy
- Integrated Structural Biology Infrastructure
- Upgrade of European Bioinformatics Infrastructure



Further information on these and other European research infrastructure projects can be found at <http://cordis.europa.eu/esfri/home.html>.

### **Rules for participation, Funding Rates & Calls for Proposals**

C. Berens set out the rules for participation in these projects. Only electronic submissions will be considered for a minimum number of participants per country. Page limits will be set. Three independent legal entities will be set up in three different countries. Candidates will now be judged according to 3 evaluation criteria: scientific excellence, impact and implementation (including relevance to the work programme's objectives). Funding rates were also presented, and the various funding percentages allowed to different types of applications were quoted.

Clause 2.4.4 of the Call for proposals covers RD. It includes trans-European natural history studies, pathophysiology, development of preventive, diagnostic & therapeutic interventions, and rare Mendelian phenotypes of common diseases.

For information sources, members were advised to use the following web addresses:

EU research: <http://ec.europa.eu/research/>

FP7: <http://cordis.europa.eu/fp7/>

Research programmes and projects: <http://cordis.europa.eu/>

Latest info on IMI: [http://ec.europa.eu/research/fp6/index\\_en.cfm?p=1\\_innomed](http://ec.europa.eu/research/fp6/index_en.cfm?p=1_innomed)

Latest info on ERC: [http://ec.europa.eu/erc/index\\_en.cfm](http://ec.europa.eu/erc/index_en.cfm)

The Commission encourages all interested parties and RDTF members in particular to register as an expert via the following web address: <https://cordis.europa.eu/emmf7/>

Members were also strongly urged to get involved in the Rare Disease Research: Building on Success" Conference taking place in Brussels on 13 September 2007.

### **Discussion**

A. Montserrat confirmed that it was possible to invite some project leaders from the FP6 to consult with the RDTF and C. Berens emphasised how important it was that they contribute to the debate. It was now important that the appropriate people be selected to do this.

It was asked why only 6 areas for RD were taken into account, and these did not include dermatological diseases. C. Berens replied that the Commission had thought about this and decided it was impossible to cover all RD on a limited budget, so it preferred not to fund too many projects to avoid time-wasting. However, she stressed the importance of taking into account remarks received and confirmed that the Call criteria would be redefined, although the limited budget would unfortunately prove restrictive in this area.

A member asked about the objectives on the Conference on RD Research. C. Berens replied that the aims of the conference were to provide the RD community with a forum to express their needs in terms of research, to provide the Commission with a strong basis for FP7 calls for proposals, and increase the visibility of RD research and thus benefiting all of the RD community. The beginning of the FP7 coincides with the date of the RD Research Conference so it will attract a lot of attention.

Another member pointed out that one objective should be to try to simplify Call application forms to help scientists fill them in properly. C. Berens said the Commission was working hard to improve and simplify these forms. For example, repetition of questions would be avoided in the future to avoid wasting time for scientists having to re-write their proposal applications.

## **D. Presentation on the Community Public Health Programme 2008-2014**

John Ryan  
European Commission  
DG SANCO Health Information Unit

J. Ryan stated that the Council agreed on the new Public Health Programme necessary for the coming 2008-2014 period, which would include 3 strands: Health information and knowledge, Health threats and Health determinants. Unfortunately, funding is limited and will be spread thinly over 7 years to 27 or 28 MS. This means that the same funding will be distributed to more MS for a longer duration (7 vs. 5 yrs). This meant it was essential to take a hard look at other means of resource, such as involving neighbouring countries. Nevertheless, the PH Programme will help RD to stay “on the radar screen”.

With regard to the Communication on RD, J. Ryan pointed out that the Luxembourg RD Conference in 2005 had constituted a major event that contributed to the recognition of RD on the policy level. More was required than projects alone so it was decided that a Communication was needed to look at health aspects. It was important to contact colleagues to contribute so that the Council Recommendation can be made. The RDTF should be mobilised to identify areas for recommendations.

### **Discussion**

A discussion regarding the content of the Communication began. The following topics were discussed and proposed to be included:

#### European Approach to Genetic Testing (GT)

An OECD report shows a large flow of specimens across borders especially for RD. This now raises the issue of specimen mobility and all related aspects such as European-wide regulations harmonising quality control and ensuring confidentiality. Among the problems is the heavy cross border flow of specimens due to the lack of expertise at the MS level. The report of Institute for Prospective Technological Studies (IPTS) 2003 in Seville provided a clear analysis of GT development issues. Tests are usually available only when translation is available but the decision is left to RD researchers. It is an area in which the US has already taken initiative by developing a network of six laboratories providing testing for extremely rare diseases at the lowest possible cost (February 2007).

J. Ryan agreed that the Commission was interested in developing cooperation with the US. The NIH's Office of Rare Diseases was also keen to cooperate and was seeking to emulate Europe's achievements in this field.

#### Patient Mobility

A public consultation is currently up and running on the DG SANCO website regarding patient mobility and the implications of this problem. One of the chief questions to address is the definition of reimbursement rights for patients. The deadline for consultation is 31 January 2007.

### Regulation of Orphan Drugs

Harmonising the assessment of the clinical utility of orphan drugs across MS will speed up the time between market authorisation and availability, thus allowing patients to face shorter waiting periods for medicinal products to arrive on the market. It is suggested that this harmonisation can be achieved by conducting assessment at the European level with the possibility of one agency sharing the load of this work. J. Ryan added that there is an EU project funding the collaboration between Health Technology Assessment (HTA) agencies in the MS, specifically for this purpose. It is coordinated by the Danish HTA agency.

### Other topics

Other topics raised as needing to be included in the Communication include:

- Trans-Atlantic collaboration
- Pooling of resources -( i.e. establishment of a network of biobanks, European-wide registries of patients)
- Support of patient support groups at the European level
- Increased sharing of data at the European level (such as Orphanet)
- Establishment of good clinical practice guidelines
- Facilitating multicentric clinical trials
- Development of telemedicine

## **E. Presentation on Rare Disease Task Force Secretariat**

Ségolène Aymé  
Orphanet  
INSERM-SC11

The structure and functions of the RDTF and RDTF Secretariat are available on the RDTF website <http://www.rdtf.org>.

### **Newsletter**

RDTF Secretariat has continued the publication of the RDTF electronic newsletter, OrphaNews Europe. Currently distributed to more than 7,000 registered readers from 28 countries, subscribers are free to opt in or out of the service at any time. Since its creation in June 2005, 16 issues have been completed. In May 2006 a satisfaction survey reflected a high level of readership satisfaction and suggestions to expand topics covered in OrphaNews Europe to include more relevant issues on the political level and in research findings. All stakeholders including RDTF members are encouraged to send their contributions.

### **Working Groups**

#### Working Group on Centres of Reference

The Working Group on CR held its last meeting in September 2006. Several conclusions and recommendations resulted from this meeting and can be investigated in more depth in the publication “Centres of Reference for rare diseases in Europe: State-of-the-art in 2006 and recommendations of the Rare Diseases Task Force” available on the DG SANCO website under RD. It was agreed that a common label was necessary for such centres as an indicator of quality for patients and health care providers (particularly with regard to reference networks already in place) The term ‘Centre of Reference’ was not currently used by many MS and definitions of them still differed. Thus far, CR for RD only exist in the following countries: Denmark, France, Italy and Sweden. Experts on rare diseases are also not abundant and often only found on the international level, further implicating the importance of CR in Europe to make research most efficient. Coordination of clinical research relevant to RD was also identified as an obstacle. As such, the following recommendations were made to the Commission:

- 1) To fund reference networks of centres of expertise for RD
- 2) To open its call for proposals to the definition of a methodology to assess the benefit from such networks from the perspective of a range of stakeholders
- 3) To encourage of the development of electronic services in the RD field

The Working Group on CR is dedicated to reaching its goal as a step forward for the improvement of the delivery of care for RD patients. The achievements of this working group can serve as a model for other medical sectors such as severe chronic diseases. Members were invited to follow the developments of this working group via the RDTF website. A new report on methods assessing the added-value of CR and the added-value of reference networks will be published by the end of 2007.

#### Working Group on Coding and Classification

This working group held its first workshop on 11 October 2006. The objectives of this working group include the collaboration between organisations that code RD. Some contacts have already been established and an exchange of RD coding and classification tables will occur between Orphanet and these organisations to coordinate codes. The final aim is to improve existing coding systems regarding rare diseases (ICD-10, Snomed, MeSH, MeDRA) to increase their visibility in information systems. The group will work on the establishment of a database of expert classifications of rare diseases. This is currently being done by Orphanet and should be released by the end of 2007.

The members of this working group include RDTF members who have volunteered, experts of RD directly involved in the classification effort, coding experts in the field of genetic diseases, and coding experts for death certificates.

In April of 2007 the revision of the WHO’s ICD-10 to ICD-11 will officially be launched. The WHO is considering involving the RDTF Working Group on Coding and Classification in this process.

#### Working Group on Indicators

The first meeting of this working group took place in Paris on 30 Jan 2006. The following areas were identified as requiring action:

- Prioritisation of RD for surveillance
- Feasibility of using death certificates for RD
- List of macro-indicators
- Mapping of existing sources of epidemiological data

Members expressing interest in the participation of future workshops include: **J. Donadiou, M. Posada de la Paz, Claire Webb, and D. Taruscio**. The date and agenda for the 2007 meeting remain to be decided. It has been proposed that the next meeting will include a follow up on on-going projects and preparation of a report.

### Future Initiatives

The future initiatives of the RDTF Secretariat include

- an updated version of the “Inventory of Community and national incentive measures to aid the research, marketing, development and availability of orphan medicinal products”
- the addition of a permanent section in OrphaNews Europe about genetic testing in collaboration with EuroGenTest (NoE)
- preparation of the RDTF work programme for 2008-2010.

## **F. Presentation on the Eurordis Workshop on European Centres of Reference**

Christel Nourissier  
Representing Eurordis

The RAPSODY (Rare Disease Patient Solidarity) Workshop, coordinated by EURORDIS, the European umbrella organisation for patient groups aims at facilitating a discussion on CR for RD at the national level. National workshops will be organised to review current proposals for the creation and development of centres of reference in the national context. A set of recommendations and a synthesis will be developed during a European Workshop in Prague in July 2007.

There was concern that many of the national workshops had not yet occurred. It was assured that all speakers would be contacted on the national level by patient organisations as soon as possible.

There was a concern that not all MS could be included in this debate, but due to the limited funding of the project countries were chosen on a volunteer basis and not all MS volunteered.

C. Nourissier reminded members of the upcoming European Conference on RD in 27-28 November next year in Lisbon, to be held as part of Portugal’s EU Presidency Programme (also part of the RAPSODY contract). This major event was designed to focus political attention on RD actions in Europe.

## **G. Conclusions**

## **Final Thoughts**

Members were encouraged to send their comments or further suggestions regarding the Communication. All topics suggested for inclusion in the Communication must now be presented in an Action Plan. The preparation of the document will start by January 2007. All suggestions should be included and any more suggestions should be forwarded to the Secretariat of the RDTF. Consultations will be advertised in OrphaNews and a member of the Communication editorial committee will soon be contacted.

## **Next Meeting**

7<sup>th</sup> RDTF Meeting will be held 21 June 2007 and will coincide with meeting of the Major and Chronic Diseases Task Force.