PRESIDENZA DEL CONSIGLIO DEI MINISTRI
Dipartimento Politiche Antidroga

DPA STATEMENT ON SCIENTIFIC INTERNATIONAL COLLABORATIONS

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Il Sottosegretario di Stato
alla Presidenza del Consiglio dei Ministri

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Presidenza del Consiglio dei Ministri
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1. INTRODUCTION

1.1. On July 11, 2011 a memorandum of intent (MoI) was signed in Washington between the Italian Government (Presidency of the Council of Ministers- Under-secretary to the Prime Minister's Office with delegated responsibility for Family, Drugs and Civil Service) and the American Government (Office of National Drug Control Policy - ONDCP) with the aim of institutionalising long-lasting governmental cooperation between the respective countries on drugs and drug addiction.

1.2. The Italian Government aims to respond to the drug problem with a scientific evidence based, integrated and multidisciplinary approach based at the same time and in a balanced way on two types of action: reducing demand (through prevention and the active offer of treatments) and reducing the supply of drugs (through legislative work and combating drug-trafficking).

1.3. In light of the memorandum of intent, and upon the need for the Dipartimento per le Politiche antidroga (DPA - Department for anti-drug policies) to increase the number of studies and research projects being conducted in the field of the neuroscience of addiction, it is therefore deemed both useful and appropriate to begin international collaborations with other institutional research, clinical and recovery interventions Centers/Organizations. These collaborations have the general aim of supporting research and building a network of technical resources and professional skills.

2. DPA GENERAL PRINCIPLES

2.1. The DPA and the Italian Government recognise drug addiction as a "preventable, treatable and curable illness, which often becomes chronic and is prone to relapse". They also consider the use, including occasional use, of drugs as "at-risk behaviour for the individual's physical, mental and social health" which it is necessary to prevent and to stop if it has already begun. By way of support for this approach, in Italy drug addicts and their families can find free health and social assistance at public healthcare structures. Drug addicts can make use of a series of tailored therapies on offer, i.e. which are selected on the basis of their needs and characteristics (solutions to prevent related illnesses, pharmacological therapies which are integrated with psycho-social support at out-patients or residential treatments in therapeutic communities, etc.), also in light of the change in their behaviour.

2.2. The Department considers prevention as a priority and essential to reduce drug demand. The spread of drug use must be considered a public health and social security problem: prevention initiatives must therefore be supported and maintained over time to promote healthy and safe environments and to protect the mental, creative, productive and spiritual potential of the younger generations. A strategic factor in preventing the development of drug addiction is the possibility and need for the early detection of drug use by adolescents and youngsters. Early treatment is more effective since it limits the period of exposure to drugs and to risks related to their use and, over the long term, reduces the costs of drug addiction (in terms of services and infrastructure) on the healthcare and social system.

2.3. In addition, the integrated pharmacological treatments offered by the Italian public healthcare system regard both the treatment of drug addiction and the related infectious diseases (in particular HIV infection and forms of hepatitis), as well psychiatric illness. The Italian strategy is, therefore, aimed at reducing drug use through integrated initiatives on prevention, treatment/rehabilitation, social and employment reintegration and through the application of the law and of action to combat drug trafficking and dealing. Such action aims to develop the early contact of drug addicts and occasional users with treatment centers, especially the youngest ones, and to promote their inclusion in adequate therapy programs aimed at their recovery.

2.4. The DPA also recognises that initiatives and action in the addiction field must be based on scientific evidence, on constant assessment of the practical effectiveness of the initiatives, and be based on ethics and respect of human rights.

2.5. Finally, the DPA stresses the importance of scientific research, above all in the field of the neurosciences. It is considered essential to translate the results of the research studies to the clinical and education fields and it is considered imperative to encourage contact with and creation of cooperative networks among researchers, clinical staff and rehabilitation professionals in order to make therapies increasingly effective and to direct research towards areas that are of practical use. To this end, fundamental importance is also attached to the development and activation of clinical trials aimed at assessing new and innovative medicines, and new educational processes which can help integrated treatments for drug addiction.

3. GENERAL AIMS OF THE AGREEMENTS ON SCIENTIFIC COOPERATION

3.1. The DPA promotes agreements on scientific cooperation in the field of addiction with all the international and accredited institutions in order to improve the fight against drugs. These agreements are aimed at sharing experiences and researches involving actively clinical, research and prevention interventions Centers in Italy sharing the National Drugs Action Plan and related to collaboration centers funded by DPA. The cooperation aims at:

a. being able to share scientific information between Italian and American organisations which are involved in the initiative, including through the dissemination, promotion and facilitation of access to the scientific information which is already on websites and in official publications;
b. increasing and disseminating a scientific approach in the field of neurosciences of addiction and neuroimaging among operators in the public healthcare system who specialise in the prevention and treatment of addiction;
c. being able to have technical/scientific guidelines and indications to improve the Italian system in the field of research and clinical work, including through training and joint meetings;
d. promoting and supporting the development of capacity-building in research into addiction of the Italian organisations involved;
e. being able to activate research, testing and clinical studies of common interest in Italy into promising new therapies;
f. being able to exchange experiences and good practice based on scientific evidence, including through an exchange of operators.

4. SCIENTIFIC SCOPE OF PARTICULAR INTEREST FOR DPA

On the basis of the National Drugs Action Plan, the following areas of interest are considered as priority by the DPA:

4.1. **Clinical trials of promising medications**: The Italian healthcare system has outstanding facilities to develop new medication trials with a good access of patients to medical facilities and a good presence of nursing and support staff. It is reasonable and possible to begin to plan multicentric trials to realize useful studies of cocaine, opiate, tobacco and also marijuana addicts.

4.2. **Studies on Early Detection, drug testing and brief interventions:** it is important to enhance and to emphasize early detection and brief intervention. A serious problem is in fact the strong delay of diagnosis of drug use especially in the youth.

4.3. **Natural history studies of drug abusers** (taking advantage of the Italian data systems - SIND): through SIND system natural history studies could help us understand the long-term trajectories of people who have been treated. There is surprisingly little knowledge about the medical and social outcomes of drug addicts following treatment. The existing information systems in Italy should allow follow up of treated drug addicts to fill this gap in knowledge of phenomenon.

4.4. **Italian Electronic Medical Record (SIND system) and assessment of the outcome**: the Italian system for data gathering through individual patient records enables the carrying out of a series of statistical and epidemiological analyses, but they need correct data collection and processing and interpretation of information. It is necessary to foster activities for maintaining such a system and improving quality of data collection of the existing system as well as its processing. Of particular interest is improving the existing online system (MFP) at Addiction Departments to assess the effective outcome in clinical practice.

4.5. **Clinical neurosciences** with in-depth analysis above all of the cognitive-behavioural aspects and their changes during treatment. Scientific cooperation in this field should also focus training and possible studies on the assessment of the effects of initiatives (educational, psychological and social support) for the brain and its functioning, above all in relation to the development of the ability for the prefrontal control of abusive behaviour and the possible interference of drugs on brain development processes in adolescents.

4.6. **Neuroimaging of addiction**: The development and application of neuroimaging techniques in the field of addiction and Spectroscopic Magnetic Resonance are important in better understanding the mechanisms and grounds for addiction. Also in Italy some preliminary studies have shown the possibility and potential of these research programs which it is thus intended to promote and encourage at national level. It is necessary to share experiences and direct Italian researchers into this innovative and experimental field, also on the basis of the experiences which have already been accumulated by other research Centers abroad.

4.7. **Transcranic Magnetic Stimulation**: this new electromagnetic stimulation technique may find interesting applications also in the field of the various forms of addiction. Preliminary studies have shown the sense in studying and activating clinical trials on drug addicts in order to assess the real

effectiveness and safety and therefore the applicability of this technique in clinics. It is in fact possible that this could be a further form of support to be added to normal treatments and education interventions in order to improve their effectiveness.

4.8. **HIV/AIDS infectious diseases, testing & counselling and antiretroviral treatment for drug addicts**: one key area to address in the HIV/AIDS epidemic is early (as soon as possible) identification and taking into treatment of all people who are HIV positive. This could help interrupt the HIV epidemic and will help HIV positive individuals achieve improved outcomes as well. In particular, the DPA want to study how to increase the percentage of drug addicts to be tested for HIV and how to increase treatment adherence.

5. CONCRETE ACTIVITIES TO BUILD COOPERATION

5.1. **Scientific Cooperation** between the DPA and others Centers will be implemented in concrete terms by means of specific clinical projects and trials. Joint scientific research projects can be activated and developed which are supported bilaterally in financial terms to be approved project by project.

5.2. **Training programs**: the possibility is envisaged to promote common training programmes, provide teaching and seminars in reciprocal training initiatives. In particular, it is desiderable to rely on the presence of teachers from organizations, which collaborates within the national training program of the DPA, at the *Scuola Superiore di Formazione della Pubblica Amministrazione* (Public Administration Training School) in Rome.

5.3. **Cross-national training opportunities** (sharing expertise). Training of Italian researchers needs to take into account the Italian academic and clinical environment. It is desirable to develop a concrete sharing and a possible exchange of professional in the field of research and clinics in order to gain best practises and innovative ways of research and clinical treatment as well as prevention modalities, in the field of education interventions and recovery.

5.4. **Workshops and congresses**: it is useful to organise conferences and workshops in Italy, with the participation of foreign guests, on issues which will be jointly agreed to be of interest, in order to encourage cooperation and the analysis of specific scientific issues within the scope of the areas of interest set out above. These events are also aimed at encouraging good practices.

6. ORGANIZATIONAL ARRANGEMENTS OF THE COOPERATIVE RELATIONSHIP

In order to make cooperation concrete, possible and effective, the following means of organisation and planning have been identified:

6.1. National network

The DPA will promote involvement in the studies by the national networks of the pre-existing cooperative centres, by encouraging the voluntary adherence of research and clinical units, as well as Regions, and by selecting the units interested in the projects which will be activated on the basis of the interest shown and the real operational and technical scientific capacities.

6.2. **Specific projects**

Then every activity which it is planned to undertake will be formalised in a specific project agreed between the DPA and International collaboration Center/Organization where the objectives, lead-times, reciprocal costs, respective duties and means and processes of working will be clarified and listed in detail.
On the agreed projects, the DPA will support these networks in financial and organisational terms and International collaboration Center/Organization will proportionately support the remaining cost needed to undertake the research.
All the projects should be according to National Drug Action Plan.

6.3. **Operative coordination**

All the organisations involved in Italy will be coordinated by the DPA (also through a cooperation centre to manage the technical and practical aspects, which will be identified step by step by DPA and charged on the basis of scientific issues to be dealt with) and International collaboration Center/Organization, for the initiatives envisaged for Italy, will refer exclusively to the Department. Relations with the operative units in Italy will be handled through the DPA and by the cooperation centre.
Any other forms of cooperation in Italy must be coordinated with those supported by the DPA in cooperation with International collaboration Center/Organization and the activities promoted with DPA funding must always be undertaken in agreement with and with the coordination of the DPA.

7. PERMANENT WORKING GROUPS

7.1. **Strategic coordination (Steering committee)**

In order to permit ready coordination and organisation of the planned activities, for each international collaboration, a permanent working group will be set up by DPA. The group will be responsible for strategic direction and general coordination, only for the scientific aspects, and it will be composed of representatives identified by International collaboration Center/Organization.
For the DPA participants to strategic coordination will be: Giovanni Serpelloni, Elisabetta Simeoni and Roberto Mollica.

Other members may be added, in agreement between the parties, during the activities on the basis of the organisational and scientific needs which could emerge. It is planned to hold at least one meeting a year and teleconferences will be used frequently in order to facilitate contacts and decrease costs.

7.2. **Working group for operational coordination**

As for the aspects of operational coordination (including possible recruiting staff into clinical and research structures) and the direct contact with the clinical structures, an "DPA international collaboration" point will be used in Italy at a clinical Cooperation Centre all along the agreements, which is able to manage a series of national networks operating in the various areas of drug addiction throughout Italy. The national operational coordination point will receive scientific strategic indications from the Steering Committee (DPA and International collaboration Center/Organization) and coordinate the operational units involved in cooperation in Italy through the creation and maintenance of networks and of the Regions involved. The operational coordination group includes: Luigi D'Onofrio, Mauro Antonelli, Elena Zappalorti,Teodora

Macchia, Marcello Chiarotti, Maurizio Gomma, Oliviero Bosco, Marina Malena, Francesco Bricolo, Franco Alessandrini, Giada Zoccatelli, Claudia Rimondo, Marco Diana and Bruno Genetti.
Other members may be added by DPA during the activities on the basis of the organisational and scientific needs which could emerge.

8. FINANCING AND COSTS

Each organisation will meet its own mission costs. Any costs for the realisation of the projects will be assessed and agreed for each individual project. It should be within the available resources and according to rules and general provisions of professional and administrative conduct.

9. GENERAL PROVISIONS

All the collaboration agreements, the projects and various activities carried out should be coherent, abiding and according to legislations, regulations and political directives of respective countries and organizations involved.

Signature

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Signature

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