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WHO/EDM/TRM/2004.1

**Report of WHO Workshop
on Regulation of Herbal Medicines
in the European Region**

**Yerevan, Armenia
22 - 24 September 2003**



World Health Organization

**Regional Office for Europe
Copenhagen**

**Traditional Medicine
Geneva**

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Introduction

The results from the WHO Traditional Medicine team (TRM) Global Survey on National Policy on Traditional/Complementary/Alternative Medicine and Regulation of Herbal Medicines show that the European herbal medicines market in developed countries, such as Switzerland, as well as in transitional countries, such as the Czech Republic, Turkmenistan and Bulgaria has nearly doubled in sales from 1999 to 2001. With growing demand for herbal medicines, the Newly Independent States (NIS) and countries in Central and Eastern Europe (CCEE) are striving to develop and incorporate national policies and programs for the regulation of herbal medicines where such policies are lacking or are in their initial stages.

Currently, with the growing demand for traditional medicine, Europe represents the single largest commercial market for medicinal plants and herbal medicines in the world. European countries are not just importers, they also have a large number of producers of medicinal plants and herbal medicines. European consumers often look to herbal medicines as a form of alternative treatment to conventional medicines. In addition, as many patients in Eastern Europe pay for health care themselves, the difficult economic conditions mean that they are often unable to afford the more expensive conventional medicines, leading them to seek alternative medicines, such as herbal products. European Union countries already have well-established national policies and programs to regulate and monitor herbal medicines. However, NIS and CCEE regions are in the process of developing and implementing such policies and programs, and are looking for specific guidance and experience in this area.

The results from the WHO-TRM Global Survey on National Policy on Traditional/Complementary/Alternative Medicine and Regulation of Herbal Medicines also showed that the challenges faced by the Eastern European countries relate primarily to their lack of research data and of education and training for national experts. Many countries lack a national policy and system of regulation of traditional and complementary medicine; and, if such a policy exists, it often excludes herbal medicines, which are instead grouped under conventional medicines. As herbal medicines are more complicated than conventional medicines, because they often contain more than one component, national drug authorities lack the knowledge and technical expertise to evaluate the safety, efficacy and quality of herbal products. In many countries in the NIS and CCEE regions, a safety monitoring system, if it exists, often does not include herbal medicines.

With these issues in mind, a workshop was conducted by WHO to share experiences and exchange ideas on development of regulatory systems and medicinal policies between participants from countries within the EURO region.

The Regional Meeting was funded by the Government of the Grand Duchy of Luxembourg. The World Health Organization expresses its appreciation to their valuable contribution.

Objectives of the workshop

In order to assist countries in meeting challenges and to identify proper approaches to regulating the safety and quality of herbal medicines discussed above, and to ensure their prudent use, WHO has developed a series of policy and technical documents. The objectives of the current workshop are to:

- ♦ Discuss the WHO Strategy for Traditional Medicine and other relevant WHO documents and guidelines for the development of regulatory systems for herbal medicines;
- ♦ Analyze the main issues and difficulties and share country experiences as regards the regulatory situation of herbal medicines;
- ♦ Discuss the minimum requirements for the regulation and registration of herbal medicine products for the participating countries.

Overview of the workshop

Twenty-three participants from Armenia, Estonia, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Romania, Slovakia, Tajikistan, Turkey, Ukraine and Uzbekistan attended the workshop.

The workshop was attended by Mr Shuichi Ohno, Director, Department of International Affairs, The Nippon Foundation, Japan; Dr Konstantin Keller, Director, Federal Institute for Drugs and Medical Devices, Germany; and Dr Ye Zuguang, Head, Division of Evaluation and Surveillance on Drug Quality, Department of Pharmacology and Toxicology of Traditional Chinese Medicine, State Drug Administration, People's Republic of China.

The Workshop was opened by the Minister of Health of Armenia, Dr Norayr Davidyan. Dr Jonathan Quick, Director of WHO, Department of Essential Drugs and Medicines Policy, welcomed participants on behalf of WHO, and Mr Kees de Joncheere, Regional Adviser on Pharmaceuticals, WHO/EURO made a briefing of the workshop. The participants selected Professor Emil Gabrielyan, Director of the Armenian Drug and Medical Technology Agency to be the Chairperson of the Workshop and Dr Tatyana Garnik, Head, Committee on Traditional and Alternative Medicine, Ministry of Health of Ukraine, to be Co-chair.

Dr Xiaorui Zhang presented an overview of the situation of national policy and regulation of herbal medicines among countries in the WHO European region.

The following issues were discussed for each country:

- ♦ the situation concerning the use of traditional medicine and complementary and alternative medicine (TM/CAM);
- ♦ the major challenges in this field; and
- ♦ the possible actions required at country level and expectations from international collaboration.

There are different ways in which traditional/herbal medicines are defined, and countries have adopted different approaches to ensure their quality, safety and efficacy.

The legislative approaches for traditional/herbal medicines vary from country to country and can be categorized as follows:

- ♦ Same regulatory requirements for both conventional medicines and herbal medicinal products;
- ♦ Exemption from general regulatory requirements for traditional medicines;
- ♦ Traditional/herbal medicines are subject to all regulatory requirements.

In some countries, traditional/herbal medicines are well established, whereas in others, they are regarded as food with no therapeutic claims allowed. NIS

countries have a large number of traditionally-used herbal medicines, but there are very few legislative criteria for their regulation.

The issues of quality, safety and efficacy of traditional/herbal medicines still remain the most important concern for all countries. The challenge is to ensure that traditional/herbal medicines are regulated properly and can, thus, be used appropriately. The problems in countries, as defined by participants, are listed below:

- ♦ Lack of legislation on traditional medicine in general and in the area of herbal medicines in particular;
- ♦ Lack of collaboration and information exchange in the field of traditional medicine among NIS countries;
- ♦ Insufficient education on rational use of traditional medicine;
- ♦ Unlike the case of conventional medicines, there are no proper definitions and classification of herbal medicines
- ♦ It is difficult to identify the active components, because there are often many components in finished herbal medicinal products based on herbal medicines;
- ♦ Insufficient specialist knowledge and technical requirements for developing good practices in the cultivation and collection of medicinal plants.

Workshop participants presented their vision of possible actions at country level and the expectations from international collaboration. The countries strongly urge WHO to provide technical and financial support for capacity building at country level and to promote proper use of traditional medicine.

The participants were requested for their views concerning possible changes to be made at country level in the four areas of the WHO Traditional Medicine Strategy.

Policy

- ♦ to develop and implement national TM/CAM legislation, policies and national programmes;
- ♦ to strengthen international collaboration and information exchange in the field of TM/CAM;
- ♦ to harmonize the regulatory requirements for traditional/herbal medicines;
- ♦ for WHO to provide technical assistance in developing the legislation and regulations on traditional/herbal medicines in Member States.

Promotion of the safety, efficacy and quality of TM/CAM

- ♦ to develop national guidance and standards on regulation and quality assurance of traditional/herbal medicines based on the possibility of their economic, technical and social impact for the country;
- ♦ to develop the common classification of traditional/herbal medicines based on the history of use, severity of diseases, etc.;
- ♦ to develop national or regional (NIS) monographs on commonly-used medicinal plants, as well as lists of prescription-only and OTC herbal medicines;
- ♦ to promote capacity building at a national level in order to assure safety and quality of herbal medicinal products;
- ♦ to support academic research for producing herbal medicines.

Promoting availability and affordability of TM/CAM

- ♦ to evaluate the possible impact of imported and locally-produced herbal medicines;
- ♦ to set up a network for information exchange on traditional medicine among NIS countries and to organize regional and national training workshops and seminars on good cultivation and collection practices of medicinal plants.

Promoting sound use of TM/CAM by providers and consumers

- ♦ to continue education on the rational and safe use of traditional medicine.

Safety and efficacy of herbal medicines

Dr Xiaorui Zhang made a briefing on the WHO Guidelines for the assessment of safety and efficacy of herbal medicines. She discussed the major differences between traditional herbal medicines and conventional medicines related to their regulation, and the difficulties in evaluating the safety and efficacy of herbal medicines. Regulatory authorities need to control the safety and efficacy of traditional medicines, taking into account the characteristics and theory of traditional medicine when developing approaches and methods for evaluation and regulation.

Dr Konstantin Keller introduced the European Union system for assessment of safety and efficacy of herbal medicines. Dr Keller clarified that long-term experience and the availability of published literature should be taken into account when assessing the safety and efficacy of herbal medicinal products. This implies a full product dossier for new herbal medicines and a reduced set of data for traditional herbal medicines. Safe use of herbal medicines must rely on a clear legal basis that defines responsibilities of all parties involved, including manufacturers, health professionals and regulatory agencies. If new legislation is drafted, sufficient time for implementation and training should be foreseen. Market access for traditional herbal medicines should be facilitated by Pharmacopoeial monographs and by monographs or lists providing information on safety and efficacy.

Dr Ye Zuguang introduced the Chinese regulatory system for the assessment of safety and efficacy of herbal medicines. The presentation focused on the following topics: regulatory requirements for documentation of traditional Chinese medicine (TCM), technical requirements for developing a new TCM drug, specific guidelines for chemistry, manufacturing, control, pre-clinical pharmacological and toxicological studies, as well as guidelines for clinical investigations.

Group discussion and report

Both working groups discussed the issues of safety and efficacy of traditional/herbal medicines and defined the following major problems in this field:

- ♦ classification of food supplements and medicines (defining the borderline; imported products);
- ♦ setting up and implementation of a "standards and inspection" policy;

- ♦ lack of human and financial resources in the area of traditional medicines, especially in the field of clinical trials and research;
- ♦ lack of incentives for producers to improve scientific standards, and protection of intellectual property for new research in the area of traditional medicine.

Participants discussed the possible actions to be carried out at country level:

- ♦ Development of a national policy for traditional medicine addressing e.g.;
 - Improvement of education related to traditional medicine in universities, such as post-graduate diplomas in phytotherapy/pharmacognosy;
 - Improvement of education of non-academic specialists involved in the production and distribution of traditional medicinal products;
 - Establishment of consumer information programs in co-operation with NGOs and consumer organizations;
 - Delivering easy access to authoritative information on traditional medicines for consumers and health professionals.
- ♦ Creation or further development of legislation defining requirements for traditional medicines and herbal food supplements.

It was also agreed that with the aim to strengthen the international collaboration, it is necessary for WHO:

- ♦ to continue to offer a forum for exchange of experiences in the scientific and regulatory assessment of traditional medicines;
- ♦ to create a network of centres of competence in the area of traditional medicine;
- ♦ to, in co-operation with interested parties, analogous to the International Conference of Harmonization, organize meetings with a view to establishing common technical requirements and scientific standards for the registration of herbal medicinal products;
- ♦ to support subregional meetings between Member States in order to pool specific competence and create uniform standards for scientific assessment and registration at a subregional level.

Quality control of herbal medicines

Introduction to WHO guidelines for the requirements of quality control of medicinal products, including Good Sourcing Practices (GSP) and Good Manufacturing Practices (GMP) guidelines and activities for quality control (Dr Xiaorui Zhang)

The presentation covered the following topics: minimum requirements for the quality control of herbal medicines, such as plant identification, purity testing, and quality control methods. Dr Zhang introduced WHO technical guidelines related to the quality control of medicinal materials, including good agricultural practice and good field collection practice, good manufacturing practice for herbal medicines, sanitation and hygiene.

Introduction to European GAP guidelines for quality control (Dr Konstantin Keller)

The presentation highlighted the need for reproducible quality of herbal medicinal products to rely on a clear set of quality assurance activities. Quality can only be assured if the manufacturing process, including agricultural production, is controlled and if the starting materials, intermediate and finished products are tested for compliance with specifications.

Introduction to Chinese Good Agricultural Practice (GAP) and other regimes for the quality control of medicinal plant materials (Dr Ye Zuguang)

The following topics were described: development of Traditional Chinese Medicines (TCM), TCM production, GAP, Good Manufacturing Practice (GMP), Good Sourcing Practice (GSP), Standard Operational Procedures (SOP) in cultivation, use of pesticides, package, transportation and storage, cooperation between farmer, manufacturer and scientific institutes. Dr Ye concluded that because herbal medicinal products may contain several herbs, specific methods need to be applied for their quality control.

Group discussion and report

Medicinal plants are used throughout the industrially developed and developing countries as medicines and raw materials for pharmaceutical industry, and represent a significant part of the world market for medicines. Therefore, it is vital to develop internationally-accepted guidelines for quality assurance.

The following challenges in quality control of traditional/herbal medicines were identified in the participants' countries:

- ♦ Compliance with high-technology standards for quality control in view of limited financial and personal resources;
- ♦ Implementation of GACP/GMP standards in small companies and of GACP in rural communities;
- ♦ Quality control of raw materials that are not subject to a licensing procedure and that may be sold in and outside pharmacies;
- ♦ Access to authentic botanical reference material and analytical reference substances;
- ♦ Import of products that do not comply with national quality standards and that may be available at a much lower price;
- ♦ Import of "exotic" herbal medicines, i.e. those not well known to Western medicine, without any documentation on quality.

The following measures were discussed as a means to overcome the problems and challenges identified:

Development of a national policy for quality assurance/quality control;

- ♦ Stepwise implementation of that national policy in co-operation and consultation with stakeholders, such as farmers, wholesalers of herbal drugs and pharmaceutical companies;
- ♦ Adaptation of requirements to national scientific and economic resources;
- ♦ Creation of national centres for analytical control of herbal medicines that dispose of the appropriate analytical resources to comply with modern standards in quality testing;

- ♦ Facilitating access to reference substances for small companies and providing support to small pharmaceutical companies for validation of analytical methods.

In order to facilitate the implementation of the commonly-accepted approaches on quality control of traditional/herbal medicines:

- ♦ WHO should continue to provide technical guidance on quality control and quality assurance for herbal medicinal products;
- ♦ WHO should stress the importance of implementation of GMP and quality standards in exporting countries;
- ♦ WHO should adapt technical requirements to the resources of developing countries and small producers of herbal medicines without creating double standards (the concept of "appropriate quality");
- ♦ WHO should update available guidelines on terminology on the quality control/quality assurance of herbal medicinal products;
- ♦ WHO should organize specific regional training workshops for Quality Control, GACP and GMP;
- ♦ WHO should establish a network of experts or centres of competence for questions related to the validation of analytical methods and should provide information on the access to authentic reference substances;
- ♦ WHO should facilitate access to guidelines by making them available on the Internet.

Safety monitoring of herbal medicines and consumer education

Introduction to WHO guidelines and activities for monitoring the safety of herbal medicines (Dr Xiaorui Zhang)

The current WHO global drug safety monitoring system and its operating mechanism was introduced. Drug safety monitoring is a relatively new area and only 68 Member States have established their own national drug safety monitoring systems which mostly do not include herbal medicines. The WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems, which are under development, will help member states address this gap and will contribute to the promotion of the safe use of herbal medicines. Dr Zhang also made a briefing on WHO guidelines for consumers on the proper use of traditional medicine. She focused on major problems in the use of TM/CAM by consumers.

Introduction to safety monitoring of herbal medicines in European countries (Dr Konstantin Keller)

Pharmacovigilance should be a legal obligation for manufacturers and regulatory agencies. It requires identification of licensed herbal medicines and other herbal substances available on the market. Reporting on herbal medicines should make use of established pharmacovigilance systems. Guidance should be provided for submitting reports and for clearly identifying herbal medicines in existing medicines databases. All activities should involve experts in the area of herbal medicines, including traditional medicine practitioners.

Introduction to methods for analysis of cases of adverse effects by herbal medicines (Dr Ye Zuguang)

The following topics were addressed: safety-related events of TRM, interactions of herbal medicines with other medicines, progress in post-marketing surveillance (PMS) and in surveillance of adverse drug reactions (ADR) in China from 1990 to 2002.

Group discussion and report

Working groups discussed the issue of safety monitoring of traditional/herbal medicines and consumer education, and agreed that major problems exist in the collection of information on ADRs related to traditional medicines and in data analysis.

- ◆ The situation cannot be improved by legislation on safety/ pharmacovigilance alone. These must be complemented by providing appropriate information to consumers on:
 - the possibility that “natural products” may cause ADRs;
 - proper use of traditional medicines;
 - reporting suspected ADRs to the doctor, pharmacist or other health professional.
- ◆ Health professionals should be trained on how to recognize possible risks of traditional medicines as an integral element of their professional education.
- ◆ Health professionals should be encouraged to report adverse events and to recognize them as a normal phenomenon of the use of a medicine.
- ◆ Health professionals should be educated that transmitting ADRs is a valuable contribution to improve safe use of medicines rather than “transmitting bad news”.
- ◆ A legal framework on advertising should include traditional medicines classified as medicines or as food supplements.
- ◆ Agencies should use all available media to inform consumers in a proactive way instead of focusing on regulations on advertising.
- ◆ WHO should establish a clear terminology on the reporting of ADRs for traditional medicines.
- ◆ WHO should consider establishing “Good advertising and information practice” guidelines and should provide examples for good consumer information through the Internet.

Conclusions and recommendations

Conclusion

The participants expressed their satisfaction with the workshop to share the country experiences and information. The participants recognized that the use of traditional/herbal medicines is increasing dramatically and that, in many countries, it is the preferred form of health care. They also confirmed that many countries have a long history in the use of TM, but that TM is diverse among the countries. TM/CAM plays an important role in health care and, although most European countries have developed their national policy and regulation of TM/CAM, they are finding it difficult to put into practice. Regulation and registration of traditional/herbal medicines are not well established in developing countries, particularly in the NIS countries, where the safety, efficacy and quality of herbal products are not guaranteed. The participants appreciated the role of WHO in providing technical guidelines and information.

Recommendations

- ♦ Governments should continue to develop national policies and regulation of TM/CAM.
- ♦ Governments and countries need to appoint focal points of TM/CAM and set up a network among the countries.
- ♦ Set up linkage of database on TM/CAM among the countries by linking with the WHO EDM website to share information and experiences.
- ♦ With assistance from WHO, develop monographs on the medicinal plants commonly used in the NIS countries.
- ♦ WHO will continue to organize training workshops on issues such as the safety, quality control, good agricultural practices and safety monitoring of herbal medicines at national and international level.
- ♦ WHO should support countries in developing national policies, regulation and capacity in evaluation and assessment of herbal medicines.

Annex 1

Workshop Programme

Monday, 22 September 2003

08:30 - 09:30	<p>Registration of Participants</p> <p>Welcome Address The Honourable Minister of Health, Dr Norayr Davidyan, Ministry of Health Armenia</p> <p>Opening Remarks Professor Emil Gabrielyan Director, Armenian Drug and Medical Technology Agency</p> <p>Dr Jonathan D. Quick Director, Department of Essential Drugs and Medicines Policy, WHO</p>
09:30 - 10:30	<p>Nomination of Chairperson, Vice-Chairperson, Rapporteur and Group Chairpersons</p> <p>Adoption of Provisional Agenda</p> <p>Briefing of the Workshop Mr Kees de Joncheere, Regional Adviser Health Technology and Pharmaceuticals WHO/EURO</p> <p>WHO Traditional Medicine Strategy 2002-2005 Dr Jonathan D. Quick, EDM/WHO</p> <p>Situation on the use of herbal medicines and regulations in European countries Dr Xiaorui Zhang, Coordinator Traditional Medicine, EDM/WHO</p>
10:30 - 11:00	Coffee Break
11:00 - 12:30	Country Presentations - Discussions on the regulatory situation and current challenges focused on safety and efficacy of herbal medicines
12:30 - 14:00	Lunch

- 14:00 - 15:30 Introduction of WHO guidelines on assessment of safety and efficacy of herbal medicines
Dr Xiaorui Zhang
- Overview of the European Union on assessment of safety and efficacy of herbal medicines
Dr Konstantin Keller
Director, Federal Institute for Drugs and Medical Devices, Bonn, Germany
- Overview of Chinese regulation on assessment of safety and efficacy of herbal medicines
Professor Ye Zuguang, Head, Division of Evaluation and Surveillance on Drug Review Quality Center for Drug Evaluation
Department of Pharmacology and Toxicology of Traditional Chinese Medicine
State Food and Drug Administration, Beijing, People's Republic of China
- 15:30 - 16:00 Coffee Break
- 16:00 - 18:30 Two Working Groups:
Group 1 - Summary of major challenges and minimum requirements - Safety
Group 2 - Summary of major challenges and minimum requirements - Efficacy
- 19:00 Reception

Tuesday, 23 September 2003

- 08:30 - 09:30 Quality Assurance
Roundtable discussion of major challenges in quality control
- 09:30 - 10:30 Introduction to WHO quality control requirements, including Good Agricultural and Collection Practices for Medicinal Plants, and Good Manufacturing Practices
Dr Xiaorui Zhang
- Introduction to European Good Agricultural Practices Guidelines
Dr Konstantin Keller
- Introduction to China's quality control methods for medicinal plant materials
Professor Ye Zuguang
- 10:30 - 11:00 Coffee Break

11:00 - 12:30	Two Working Groups - Discussions Group 1 - GMP Group 2 - GACP and the quality control methods of herbal materials
12:30 - 14:00	Lunch
14:00 - 15:00	Roundtable discussion on major challenges of safety monitoring of herbal medicines
15:00 - 16:00	Introduction to WHO guidelines and activities for monitoring safety of herbal medicines Dr Xiaorui Zhang
	Introduction to herbal medicine safety monitoring in European countries Dr Konstantin Keller
	Introduction to methods for analysis of adverse effects cases of herbal medicines Professor Ye Zuguang
16:00 - 16:30	Coffee Break
16:30 - 18:00	Two Working Groups: Working Group 1 - Focus on report system on how to set up or expand the systems Working Group 2 - Focus on methods for analysis of adverse effects cases

Wednesday, 24 September 2004

08:30 - 09:30	Rational Use Roundtable discussion of major challenges in rational use focus on the consumers
09:30 - 10:00	Introduction to WHO guidelines for the consumers on proper use of traditional medicine and activities Dr Xiaorui Zhang
10:00 - 10:30	Coffee Break
10:30 - 12:30	Two Working Groups' discussion on recommendations for future development and collaborative work on the regulation of herbal medicines
12:30 - 13:30	Lunch
13:30 - 14:30	Each working group report the result of the discussion and following by discussion and adoption
14:30 - 15:30	Final conclusions and closure of the workshop

Annex 2

List of Participants

Armenia

Professor Emil Gabrielyan
Director
Armenian Drug and Medical Technology
Agency
15 Moscowian Street
Yerevan, 375001
Armenia

Tel: +3741 584020
Fax: +3741 542406
Email: egabri@pharm.am

Dr Samvel Azatyan
Deputy Director
Armenian Drug and Medical Technology
Agency
15 Moscowian Street
Yerevan, 375001
Armenia

Tel: + 3741-584020
Fax: + 3741 542406
E-mail: azatyan@pharm.am

Professor Elmira Amroyan
Head, Pharmacological Commission
Armenian Drug and Medical Technology
Agency
15 Moscowian Street
Yerevan, 375001
Armenia

Tel: + 3741-584020
Fax: + 3741 542406
E-mail: elmira@pharm.am

Professor Alexander Panosyan
Director
"ExLab" Control-Analytic Laboratory of
ADMTA
Armenian Drug and Medical Technology
Agency
15 Moscowian Street
Yerevan, 375001
Armenia

Tel: + 3749 409180
E-mail: phanos@sci.am

Estonia

Dr Ain Raal
Docent of Pharmacognosy
The University of Tartu
Department of Pharmacy
Tartu 51014
Estonia

Tel: + 372 7 375 281
Fax: + 372 7 375 289
E-mail: araal@ut.ee

Georgia

Ms Tata Megrelidze
Chief Specialist
Registration Unit of the Department of
Pharmacy
Ministry of Health
Tbilisi
Georgia

Tel: + 995 3237 1285
Fax: + 995 32 25 06 32
Mobile: + 995 77 47 80 78
E-mail: tmegrelidze@hotmail.com

Ms Tamila Shubitidze
Head
Information Unit of the Department of
Pharmacy
Ministry of Health
Tbilisi
Georgia

Tel: + 995 32 37 1285
Fax: + 995 32 25 06 32
Mobile: +995 77 47 52 46
E-mail: tshubitidze@hotmail.com

Kazakhstan

Mr Ajsulu Akhimova
Head
Committee on Pharmaceuticals
Department of Drug Registration and
Monitoring
Moskovskaya Str. 66
473000 Astana
Kazakhstan

Tel: +7 3172 31 79 86
Fax: +7 3172 31 77 89
E-mail: priem_farm@minzdrav-rk.kz

Dr Nataliya Gunko
Deputy General Director
National Centre of Drug Expertise
Abylaj khan Str. 63
480004 Almaty
Kazakhstan

Tel: + 7 3272 73 16 72
E-mail: nataliya@dari.kz
E-mail: farm@dari.kz

Kyrgyzstan

Dr Jildiz Ysikeeva
Expert, Drug Information Centre
Department of Drug Provision
and Medical Equipment
Ministry of Health of Kyrgyzstan
25,3-rd Line Street
720040 **Bishkek**
Kyrgyzstan

Tel: +996 31254 29 40
Fax: +996 312 54 29 40
E-mail: dic@elcat.kg
URL: www.pharm.med.kg

Dr Saliya Karymbaeva
Head
Drug Information Centre
Department of Drug Provision
and Medical Equipment
Ministry of Health of Kyrgyzstan
25, 3rd Line Street
720040 **Bishkek**
Kyrgyzstan

Tel: +996 312 54 29 10
Fax: +996 312 54 29 10
E-mail: ddp-me@elcat.kg
URL: www.pharm.med.kg

Republic of Moldova

Dr Larisa Solovieva
Researcher
National Institute of Pharmacy
Laboratory of Control
and Certification of Medicines
Grenoblia Str. 149a
2019 **Chisinau**
Moldova

Tel: + 373 2 727203
Fax: + 373 2 727207
E-mails: instfarm@moldtelecom.md
lccminf@moldtelecom.md

Romania

Dr Marian Nanu
Str Grigorescu nr. 19
B1 V18, Ap.97, Sector 3
Bucharest
Romania

Fax: +40 2 12 248 328
E-mail: mariannanu@yahoo.com

Slovakia

Dr Jozef Slany
Director
State Drug Policy Department
Ministry of Health of Slovakia
P.O.Box 52, Limbova 2
837 52 Bratislava
Slovakia

Tel: + 421 2 593 73 135
Fax: + 421 2 54 77 60 48
E-mail: jozef.slany@health.gov.sk

Tajikistan

Dr Khusrav Khalifaev
Head
Department of Plant Raw Materials
Scientific Research Center on Elaborating
New Drugs
Ministry of Health
69 Schevchenko str.
734025 Dushanbe
Tajikistan

Tel: + 992 372 36 42 71
+ 992 372 36 38 73

Ms Mavluda Makhmudova
Gogol str. 18/4, apt. 2
734002 Dushanbe
Tajikistan

Tel: + 992 372 21 67 07
E-mail: mavludash@mail.ru
npt.who@tajnet.com

Mr Mirzo Nazarovic Nazarov
Faculty of Pharmacognosy
Mayakovskogo str. 75/4, apt. 42
734043 Dushanbe
Tajikistan

Tel: + 992 372 33 00 31

Dr Dilbar Norova
Head
State Scientific Centre of Drugs Expertise
Ministry of Health
5/5 Alishera Navoi str.
734042 Dushanbe
Tajikistan

Tel: + 992 372 21 19 45

Turkey

Ms Oznur Sevim Evranasoglu
 Pharmacist
 Ministry of Health
 Saglik bakanligi
 Drug & Pharmaceutical General Directorate
 Mithatpasa Caddesi No.1
Sihhiye Ankara
 Turkey

Tel: + 90 312 435 64 40/230 16 74
 Fax: +90 312 230 16 10
 E-mail: sevime@saglik.gov.tr
 znurs@yahoo.com

Ukraine

Dr Tatyana Garnik
 Head
 Committee on Traditional and Alternative
 Medicine
 Ministry of Health
 7 Grushevskoho Street
Kiev
 Ukraine

Tel: +38 044 560 88 26
 Fax: +38 044 253 60 24
 E-mail: kmi@kmiuamnev.ua
 URL: www.kmiuamn.org

Dr Valerij Pokanevich
 Senior Specialist
 Ministry of Health
 General Director
 Ukrainian Association of Folk Medicine
 President of UAFM's Medical Institute

Tel: +38 044 234 25 84
 Fax: +38 044 234 99 92
 E-mail: kmi@kmiuamnev.ua
 URL: www.kmiuamn.org

Uzbekistan

Ms Mukhabat Ibragimova
 Head
 Bureau on Registration of the Main
 Administrative Department of
 Pharmaceutical
 and Medical Equipment Control
 16 Umarov Str
Tashkent
 Uzbekistan

Tel: +998 71 144 48 23
 Fax: +998 71 144 48 25
 E-mail: uzpharm@online.ru

Short-term consultant

Professor Ye Zuguang
 Head
 Division of Evaluation and Surveillance on Drug Quality
 Department of Pharmacology and Toxicology of Traditional Chinese Medicine
 State Drug Administration

People's Republic of China
A 38 Beilishilu
Beijing 100810
People's Republic of China

Observers

Mr Shuichi Ohno
Director
Department of International Affairs
The Nippon Foundation
1-2-2 Akasaka Minato-Ku
Tokyo 107-8404
Japan

Dr Konstantin Keller
Head,
Federal Institute for Drugs and Medical Devices
Division Particular Therapeutic Systems
Kurt-Georg-Kiesinger-Allee 3
53175 Bonn
Germany

Telephone: +49 228 207 5335
Fax: +49 228 207 5395
E-mail: k.keller@bfarm.de

Interpreters

Ms Yelena Avanesova
Interpreter

E-mail: avanesova@yandex.ru

Mr Andrey Kust
Interpreter

E-mail: andrewkoust@yahoo.com

World Health Organization

Headquarters

Dr Jonathan D. Quick
Director
Department of Essential Drugs and Medicines Policy

Telephone: +41 22 791 3834
E-mail: quickj@who.int

Dr Xiaorui Zhang
Coordinator
Traditional Medicine

Telephone: +41 22 791 3639
E-mail: zhangx@who.int

Regional Office for Europe

Mr Kees de Joncheere
Regional Adviser
Health Technology and Pharmaceuticals

Telephone: +45 39 17 14 32
E-mail: cjo@euro.who.int