

# South East European Regional Pharmaceutical Conference

**Report on a WHO Meeting  
Sarajevo, Bosnia and Herzegovina,  
27–28 February 2006**



## ABSTRACT

Representatives from the Ministries of Health and the medicines agencies from the countries in South eastern Europe participated in the South East Europe Pharmaceutical Conference organised in Sarajevo, Bosnia and Herzegovina, 27-28 February 2006.

The conference was part of the collaborative project executed by the WHO Regional Office for Europe and the Governments in Bosnia Herzegovina, funded by the European Commission, on health sector development in Bosnia Herzegovina, which included a large pharmaceutical component.

On the first day was the official delegates from the Ministries and the regulatory authorities discussed the current issues in the pharmaceutical sector and opportunities for collaboration in the region. The second day was for a broader audience and addressed a range of policy issues, and the possibilities for collaboration through a Council on Medicines for South East Europe.

The meeting concluded on the need and usefulness to have a more permanent platform for collaboration on pharmaceutical policies through the establishment of a Council on Medicines. This will be discussed with the authorities in the Ministries and with external donors for possible support; and the collaboration will be taken up within the framework of the Stability Pact.

### Keywords

PHARMACEUTICAL PREPARATIONS  
DRUG AND NARCOTIC CONTROL  
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DRUG UTILIZATION  
DRUG INDUSTRY  
ECONOMICS, PHARMACEUTICAL  
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## Introduction

Representatives from the Ministries of Health and the medicines agencies participated in the South East Europe Pharmaceutical Conference organized in Sarajevo, Bosnia and Herzegovina, 27–28 February 2006.

The conference was part of the collaborative project executed by the WHO Regional Office for Europe and the Governments in Bosnia and Herzegovina, funded by the European Commission, on health sector development in Bosnia and Herzegovina, which included a large pharmaceutical component.

The first day was for official delegates from the Ministries and the regulatory authorities to discuss current sector issues and opportunities for collaboration in the region. The second day was for a broader audience and addressed a range of policy issues, and the possibilities for collaboration through a Council on Medicines for South East Europe.

The countries in the SE European region have many regulatory issues and approaches in common. They are all developing and implementing their legal framework and administrative practices in line with those of the European Union (EU) and with international guidelines. These days medicines are products moving in international commerce and the issues related to the approval and monitoring of these products are very much the same in all countries.

The meeting was aimed at exploring the possibilities and the added value for the countries to cooperate through the exchange of information and experiences in medicines policies on regulation and control. This initiative would facilitate the effectiveness of medicines policies and regulation to the best of the patients, the governments and for the best of the domestic and the multinational pharmaceutical industry.

The meeting was organized with the official representatives of the Ministries of Health on day one, while on day two a wider audience also from the private sector attended.

In the opening statements the Minister of Civil Affairs and representatives of the Ministries of Health in Bosnia and Herzegovina indicated the importance of the project, and referred to the draft law on pharmaceuticals that would now harmonize regulatory practices in the country. They expressed the importance for SE European collaboration in this area and highlighted the success of similar efforts in other areas through the Stability Pact initiatives.

The EU ambassador to Bosnia and Herzegovina called the project a resounding success, and reiterated the importance for subregional collaboration through a Council on Medicines, as a means to improve pharmaceutical policies for the benefit of patients.

The WHO Regional Office for Europe expressed the importance of the health reform project in Bosnia and Herzegovina, and referred to the overall objectives of national medicines policies in terms of ensuring equitable access to safe and effective medicines of good quality, enhancing their appropriate use, and getting value for money of societies' investment. WHO stressed the need for international collaboration in the medicines sector, and referred to the need of having a more permanent platform for discussion.

## **Results and Conclusions**

The discussions on the width of issues addressed in the conference reiterated the importance for the countries in SE Europe to come together and to learn from each other's experience and provide opportunities for communication and cooperation in the future. The delegations from all participating countries welcomed the idea of establishing a Council on Medicines. This idea has been put forward in previous years, and it was felt that it was the right time to advance these proposals. This Council would be a “loose” networking arrangement among interested countries, and focus on the exchange of information and learn from each other experiences. It would have no legal implications for national decision making. The Council would have a Management board (composed of Ministry of Health representatives) and function through an executive secretariat.

The Council would add value to the national programmes by providing better information for better national decision making, through achieving efficiency gains, by sharing instruments and technical documents, and through opportunities for training and capacity building for national experts. It would be fully in line with international initiatives towards increased collaboration in the pharmaceutical sector.

This collaboration could cover the areas of medicines regulation, inspections and post-marketing surveillance as well the fields of provision of medicines, appropriate prescribing and use of medicines, and good pharmacy practice.

A possible timetable would include a discussion on the Council at national level, a further completion of the Council proposal and exploring external support for the Council, confirming the expression of interest from the Ministries of Health, and possibly presenting the Council proposal for discussion and adoption by the Stability Pact Ministerial meeting in June 2006 in Sarajevo.

## **Summaries of conference presentations**

### **Session 1: Medicines policies**

Dr Ljiljana Stojanovic from Republic of Serbia gave an overview of what a National Medicines Policy would be, why it should be developed and its importance. The policy should define a set of society goals on access to medicines and a strategy to reach these goals. The medicines policy in broader sense should promote equity and sustainability of the pharmaceutical sector, and more specifically aim at providing access to quality medicines and support the rational use of medicines. Goals that are more specific are to be defined depending on the country situation, the national health policies and the political priorities. Key components of a policy document will be: selection of essential medicines, affordability, medicines financing, supply systems, regulation and quality assurance, rational use, research, human resources, monitoring and evaluation. As an example, Serbia had developed its first draft document in 2003 and developed an updated version in 2005. Other countries in the region are also updating their medicines policy documents.

In the following discussion, participants presented their national perspectives and policies and reiterated the importance of having a comprehensive and cohesive approach towards the pharmaceutical policy issues.

## Session 2: Regulation of medicines

A survey study of regulatory activities in the South East European Countries was undertaken by the WHO Regional Office for Europe, and the results presented by Mr Kees de Joncheere and Mr Ola Westbye. Most of the responding countries reported that a rather comprehensive regulatory mechanism is in place: this is regulation of manufacturing, importers, wholesalers, pharmacies, inspection of manufacturers, wholesalers and pharmacies, control of imported and exported products, quality control of marketed products, monitoring of adverse reactions, approval of clinical trials, price control, information activities and support to rational prescribing. It is important to notice that many countries already have made a new medicines law in accordance with the EU legislation, and others are aiming at developing EU-harmonization in near future, however full implementation is the challenge. The countries are also modernizing their regulatory authority by establishing an agency according to models in EU-member states.

Bosnia and Herzegovina has recently developed a new draft law in line with EU legislation that is foreseen to be adopted by Parliament in near future.

Dr Czaba Haraszti from Hungary reported on recent updates of the Hungarian legal framework as a consequence of joining the EU. A long list of amendments had to be introduced. As a result of introducing EU-standards for documentation of quality, safety and efficacy approximately 1600 products were deleted from the list of marketed products. The rule on data exclusivity is still not settled (Hungary is asking for 6 years in stead of the 8+2+1 rule), but all the rest of EU-rules are fully implemented. As a result of EU accession, the competent authority (National Institute for Pharmaceuticals) has updated its organizational structure to be able to comply with the procedures and administrative deadlines stated by EU-rules. The new collaborative agreement of drug regulatory authorities of EU associated countries (CADREAC) from 24 October 2004 was presented. This allows the signature countries to approve new medicines according to a simplified procedure, provided they are having a marketing authorization in EU according to Centralized Procedure (CP) or Mutual Recognition Procedure (MRP).

Dr Vesna Koblar shared the experience of Slovenia when the country entered the EU. The country had to define what is according to EU-rule and what is not regulated in the common EU rules. EU rules are to be fully transposed into national legal systems. Initially there was considerable resistance to make changes in the existing national regulatory framework, both by national industry as well the regulatory authority, however a common understanding was swiftly reached, and the new framework was established. The consequences of this harmonization are; harmonized standards, harmonized practices, introduction of agreed changes, removing of obstacles for the industry, saving of resources, better availability to information, and better health protection. The newly established Medicines Agency had to reorganize and focus on new demands as a partner to EU cooperation (over 100 obligatory meetings per year). The agency had to focus on specific areas of expertise and become a centre of excellence, rather than being a full-scale provider, and had to become accustomed to working in a network rather than being a stand-alone agency.

Professor Sinisa Tomic discussed the establishing of a medicines agency in Croatia and the challenges in taking on board all EU requirements, both the regulatory standards and preparing for participation in the EU regulatory procedures. The Agency was established on 1 October 2003 and a new law on medicines was put into effect 1 January 2004. The agency was

established as a result of merging The Croatian Institute for Medicines Control and the Croatian Institute of Immune-biological Preparations Control. The Agency now has a staff of 98 people, including the laboratory staff. It is a full-scale agency operating according to the same standards and procedures as in an EU member state agency, and also covers medical devices.

### **Session 3: Inspection of manufacturers and wholesalers, good manufacturing practices (GMP)**

Ms Sanja Custovic presented, on behalf of Mr Slobodan Lucic, the results of an overview of pharmaceutical inspections in the region (Bosnia and Herzegovina, Bulgaria, Croatia, Hungary, and The former Yugoslav Republic of Macedonia). There was wide variation in the reporting on the violations of standards, and generally the inspections are disclosing a number of substandard services and non-compliant product standards.

Dr Hans Smallegenbroek from the Dutch Pharmaceutical Inspectorate gave an overview of the Pharmaceutical Inspection Co-operation Scheme (PIC/S). The PIC/S goal is “to lead the international development, implementation and maintenance of harmonized GMP standards and quality systems of inspectorates in the field of medicinal products”. The PIC/S is a voluntary scheme among those members who qualified for membership. New countries are constantly being considered to become new members, e.g. the U.S. Food and Drug Administration is applying for participation. The PIC/S is providing a series of publications and guidelines as well as training opportunities (training seminars, expert circle meetings, joint visits groups). The scheme can be reached by contacting the secretariat in Geneva ([www.picscheme.org](http://www.picscheme.org)). It was concluded in the discussion that the PIC/S offers a good model for international collaboration that the SE European countries could benefit from.

### **Session 4: Post marketing surveillance**

Mr Sten Olsson from the WHO Collaborating Centre for International Drug Monitoring, Uppsala, Sweden introduced the programme and the initiatives offered by the Centre to the 79 participating countries. The Centre receives adverse drug reaction reports (case reports) from all members' national centres and based on these reports a signal procedure is generated. Till date some 3.5 million reports are accumulated. The Centre is providing a series of publications and is offering training opportunities in Uppsala as well as in member countries.

Dr Aida Mehmedagic from Bosnia and Herzegovina reported on the functioning of the control laboratory in Federation of Bosnia and Herzegovina. The laboratory was inaugurated in October 2000, and extensive EU support was received under a previous project. Since then the laboratory had achieved very high standards, with accreditation (ISO 17025) and being a full member of the European Network of Official Medicines Control Laboratories (OMCL). The harmonized standards of the OMCLs in the South East European Region provide a perfect platform for more cooperation in the field. Specialization and exchange of control protocols would significantly increase the total quality assurance programmes. Especially in the field of controlling biological products, there is a need for more cooperation.

Mr Richard Wanko, representing the European Directorate for Quality of Medicines (EDQM), introduced the European Network of Official Medicines Control Laboratories (OMCL-Network). The network is a voluntary network open to all countries that have signed the European Pharmacopoeia Convention and to observers to the Pharmacopoeia Commission. Till date 90

OMCLs are involved. All members are working according to the same standards and are regularly participating in a proficiency testing scheme. The network is providing a series of other services, e.g. pre-authorization testing of new methods, characterization of reference materials, validation of pharmacopoeia methods and standardization of biological products. The network also provides a long list of training opportunities.

## **Session 5: Pricing and reimbursement schemes**

Mrs Claudia Habl, from the Austrian Health Institute introduced the pricing and reimbursement systems currently used in the EU member states. In all EU countries the medicines budget consumes a substantial part of the health budget. All member states have some kind of price regulatory mechanisms in place; it may be direct regulation of commercial prices or indirectly by regulating reimbursement levels. The reference pricing of reimbursement levels are becoming increasingly popular among member countries. Pricing and reimbursement rules are responsibility of each member state, and thus not harmonized within EU. Transparency and information exchange is now supported by the EU Public Health Directorate (DG SANCO) supported project on the Pharmaceutical Pricing and Reimbursement Information (PPRI) network. Price comparisons between countries are very difficult (or not possible) because actual prices are not always available.

In the following discussions the participants agreed that enhancing information exchange on medicines prices, reimbursement policies and reimbursement decisions would be very beneficial to the SE European countries.

## **Session 6: Rational use of medicines**

Professor Bozidar Vrhovac from Croatia provided a wide overview of the topic “Rational Use of Medicines” and gave the following definition: prescribing pharmaceuticals with proven efficacy, with acceptable risk/benefit ratio and with acceptable cost/benefit ratio (affordability). The term “relative efficacy” was introduced, meaning that the prescribing doctor must consider alternative medicines or treatments, and not only consider efficacy as an absolute best treatment for the individual patient. A set of measures was suggested to make medicines prescribing more rational and bring costs under control: Establish positive lists and reference pricing of reimbursement levels, reference price could be on equal for active ingredients, ATC-5 (anatomical therapeutical chemical classification level 5) or on similar medicines with similar efficacy ATC-4 (anatomical therapeutical chemical classification level 4), introduce “basic basket” for reimbursement, increase or introduce patient co-payment, the use of agreed guidelines and feedback to doctors on compliance to guidelines. The training and education of doctors is an important part of national programme on rational use of medicines.

Dr Jens Peter Kampmann provided the experience from the Institute for Rational Pharmacotherapy in Denmark. The need for independent information to balance advertising from the pharmaceutical industry was underlined. The institute in Copenhagen was established in 1999 as a semi-independent information unit to the Medicines Agency, having its own budget and staff, a completely free position to express any views on the use of medicines, while having access to vital information within the Agency. The institute does not have any executive power, but has a strong position because of its reliability, its credibility and persuasion. The institute is providing a series of publications via its web page, organizes meetings and lectures for doctors. A very significant contribution to rational therapy is the assessment of new medicinal products

appearing on the web site on the very first day a new product is marketed in Denmark. In Denmark all prescriptions are computerized and stored in a central computer. Every doctor has access to his own prescription pattern as well to statistical data for his colleagues. This is a tool for assessing prescription habits and for improvements. The institute is very much supporting local doctors in their academic detailing, approach, providing them with training and therapy guidance.

Professor Stephen Chapman from Keele University in the United Kingdom presented some of the British initiatives to support rational therapy. The reimbursement system in the United Kingdom uses General Practitioners' (GP) budgets, and doctors are always made aware of prescribing costs. Education of doctors and nurses are seen as key factors to successful management of (chronic) diseases. For this training, it is important to have quality assessments and evaluations of implemented measures. Communication with patients is also underlined. For better disease management the following factors were mentioned: The need for a multidisciplinary approach avoiding the "erosion" of professional boundaries, computerized decision support, quality driven contracts and services as well as changes in health care education.

Dr Emil Hristov, representing the Bulgarian Drug Agency focused on medicines information services from the Agency and the regulatory perspective on industry provided information. The Bulgarian Drug Agency is providing updated information in their Bulletin through their web site and provides extensive data on drug statistics. The information is aimed at the medical profession and to the public. The industry information, or advertising and promotion, are regulated by law, and require pre-approval by the Agency. Over the counter medicines (OTC) may be promoted to the public, and prescription medicines can only be promoted to the health profession. Out of approximately 300 controlled advertising texts per year, the Agency had to make corrections in half of them, and just 1–2 were refused completely.

Dr Gordona Damjanovska from the Ministry of Health in The former Yugoslav Republic of Macedonia presented results from introducing the "positive list" concept according to a set of defined criteria. These were adherence to National Drug Policy, the use of evidence based therapy guidelines, considering evidence based pharmacy, considering patient co-payment, using pharmaco-economic analysis, developing pharmaco-therapeutic manuals and taking into account national health programmes. The actual annual costs for different segments of therapy could be analysed, and therapy pattern influenced through modifying the positive list elements.

In the following discussion participants shared their national experiences and stressed the importance and usefulness of sharing this information among policymakers in SE Europe.

## **Session 7: Pharmacy Practice**

Ms Sanja Stjepanovic reported on the development and implementation of Good Pharmacy Practice Guidelines (GPP) in Bosnia and Herzegovina. A special project was initiated in 1998, supported by Pharmaciens sans Frontieres (PSF) and the WHO Regional Office for Europe. A first GPP Guidebook was developed in 1999 (Blue Book). Based on this book and with the support of WHO-experts training has now been provided for 496 pharmacists out of 600 registered in the country. A new version of the Blue Book is foreseen, to include more on self-care and health promotion. The GPP document is seen as an important tool for defining the

future role of pharmacists as health care providers. The implementation of GPP standards is a step-by-step process that will need some time to be fulfilled.

Mr Ola Westbye, WHO consultant, presented a model for defining a Law of Pharmacy Services. Such a law has to be defined according to national policies and priorities. There is no harmonisation within the EU in this area. The important element is to create a law that puts obligations to the pharmacies so they can play a major role as first line health providers. Optimizing the quality of services in the pharmacies, meaning services that satisfy the health needs of customers and patients, should guide the development of the law.

Ms Radojka Malbasic from the Ministry of Health of Republika Srpska (RS), Bosnia and Herzegovina (BIH), presented an overview of pharmacy inspection services in general and shared local experience from RS, and compared statistical figures from the Federation of Bosnia and H Herzegovina, Croatia, Bulgaria and The former Yugoslav Republic of Macedonia. The number of pharmacies needed varies according to national circumstances. In RS the number of inhabitants per pharmacy is 6682, compared to Bulgaria having 1890 per pharmacy. In several EU countries the ratio is approximately 2000 to 3000, but going up to 10 000–15 000. Inspection reports are revealing a significant number of violations of standards, e.g. lack of qualified staff, dispensing of non-registered products, lack of quality control of raw materials and finished galenic products as well as incomplete record keeping and reporting.

The participants discussed the importance of having a properly functioning pharmacy sector in the countries in order to improve the actual use of medicines by patients, and identified this as well as an area where international collaboration could help significantly in enhancing professional performance.

## **Session 8: Regional Cooperation**

### ***The establishment of “Council on Medicines for South East European Countries”***

The need for a more extensive and productive cooperation between the countries in the region has been discussed at several occasions in previous years. The idea to establish a permanent forum for cooperation along the model of the Nordic Council on Medicines has been proposed and was supported by the participants. A thorough discussion with all stakeholders would provide fruitful input for the further development of the idea, and for final decision making.

A Council as proposed is intended to be a forum for cooperation among regulators of medicines (Ministries of Health and Medicines Agencies) and policy makers. Participation in the Council would be on a voluntary basis, and also participation in activities organized by the council would be voluntary and be decided upon by individual agencies according to their own expected benefit. The Council would have no executive or administrative power, and solely provide technical support for common activities and information exchange.

## **Conclusions**

- The value of this conference is to come together to learn from each other's experience and provide opportunities for communication now and in the future.

- Delegations from all participating countries welcomed the idea of establishing a Council on Medicines and supported further development with enthusiasm.
- It was agreed that all delegates should inform their minister at home and prepare the ground for national decision makers.
- WHO will explore the possibilities for initial support to the establishment of the Council.
- The idea to establish a Council shall be discussed and approved by the Stability Pact Ministerial Meeting in June this year.

## *Annex 1*

### THE COUNCIL ON MEDICINES FOR SOUTH EAST EUROPE

**The aim:**

The aim is to increase the capacity and facilitating the regulation of medicines in the region – to the benefit of patients, health care services and the pharmaceutical industry.

**Background information:**

The medicines are international products entering the markets in several countries at the same time. The pharmaceutical industries are now operating on an international basis, and regulation of medicines has become a public service requiring international harmonisation and cooperation. The new medicines are very sophisticated products. Regulatory assessment of these products are very demanding in terms of having trained and specialized scientists and the necessary capacities to do the work. No regulatory agency in Europe is able to take this responsibility alone, so that is why all agencies in EU work together under the European Agency in London. Before they all joined the European procedures, the five Nordic Countries established the Nordic Council on Medicines since 1975. This was proven to be a very successful model for cooperation between smaller countries.

Now, it is proposed to establish a similar model for cooperation in the South East European Region. It is necessary to start cooperation now, even though it is foreseen that these countries might enter EU at a later stage.

**The type of organisation:**

The Council is a permanent forum for cooperation in the field of medicines regulation. It is supported by the Ministers in charge of health and fully promoted by the World Health Organisation. Participation is absolutely voluntary. Any country may declare participation or not, and participating countries are fully free to choose what activities they would like to be involved in. The council is purely a forum for agreed cooperation, and has no power or authority itself. The Council cannot make any administrative decisions, and its recommendations or guidelines cannot be binding to any of its participating countries. There is no delegation of power or sovereignty, and it is not an international organization.

However, it is a practical forum for discussions and a forum for fostering harmonisation of medicines regulation in the region. It is also a forum for organising and the sharing of workload between competent authorities in participating countries.

**The functioning:**

The council is functioning by establishing working groups, organizing training sessions, hosting conferences, providing access to information, creating links to other professional organisations, preparing the ground for sharing of work load between regulatory bodies, etc.

This is a forum mainly for the staff of ministries and medicines agencies (competent authorities) but may very well include professional staff from pharmacies, wholesalers and industry, depending on type of activity. Participation in activities shall always be voluntary and to the benefit of those taking part. The council shall normally rely on experts from the region, but may

also invite outside experts to provide special input. So, this is a forum for medicines regulators, created by the regulators themselves.

**The activities:**

The activities must be planned and undertaken as decided by the council itself. This will be influenced by the needs and interest of participating countries. A tentative list could be as follows:

*The Annual Regional Conference on Medicines.* This is a broader forum for reporting progress and presenting new aspects of medicines regulation. It might be suggested to select a few topics for each of the conferences that could be more thoroughly discussed, e.g. good manufacturing practice (GMP), clinical trial practice (GCP), adverse reactions monitoring, medicines information service, good pharmacy practice (GPP), and many others.

*The Regional Training Sessions.* These are training opportunities offered to professional staff of agencies and other professionals in the field of quality assurance and medicines assessment. Normally, this is very demanding for individual countries. Going together would save a lot of resources and increase the quality of training.

*The Medicines Bulletin for South East Europe.* This could be a quarterly bulletin updating the situation in the regulatory sector and bringing news also from other countries and the EU. The bulletin could also provide summaries from training sessions and other meetings to bring this to a wider audience. The bulletin could also invite outside writers on new and special topics.

*The Internet service.* It is obvious that the Council should open its own Internet site for transmission of news and updated developments in the medicines sector. It shall not be a site for information about individual medicinal products, but it may transmit important regulatory decisions regarding medicines or therapies. This site could also be a guide to other important sites on the net, by providing relevant links and addresses, e.g. to other national agencies, to The European Agency, to libraries, therapy guidelines, WHO collaborating centres, etc.

*The sharing of workload between agencies.* We see the same medicines now on the markets in all countries, and the agencies are doing very much the same work to assess the same products and perform the quality control on identical tablets. Much work can be saved, if the agencies can agree on sharing the assessment reports done in other (neighbouring) countries. The full scientific assessment of a new medicine may take several experts many months to do. If agencies agree on sharing the assessment work, they shall individually make their own administrative decisions afterwards. In the EU this is a binding procedure. In the South East European Region this could be a voluntary scheme. Coordination of this sharing of workload could be organized within the frames of a Council. Laboratory control of medicines is now very sophisticated science, and much could be gained from specialising the laboratories and sharing of samples and test results.

*Development of therapy guidelines (standard therapy protocols).* This is more and more based on internationally recognized evidence based standards, but has to be adapted to local traditions and to the spectrum of medicines available. The council could be a relevant forum for creating regional guidance to the rational selection and correct use of medicines.

**The organisational structure:**

For the organisational issues, a Management Board shall be established, consisting of one nominated member from each participating country. The chairman and a vice chairman shall be elected by majority voting among board members, making sure that the chairmanship is rotated among participating countries. The Board shall approve a plan of activities as well as the budget. The board shall also appoint a permanent secretary general.

A permanent secretariat shall be set up in city **xxxxx**. A secretary general shall head the secretariat and all day-to-day activities. The secretary general is expected to be a professional in the pharmaceutical sector, having broad experience from medicines regulation.

As activities grow, more professional staff and technical support may be necessary.

### **Financing:**

Each partner shall pay a membership contribution. This shall cover the basic costs for running the secretariat. For all of its services, the Council shall be entitled to charge a fee and be able to recover its expenditure as a self-financing organisation. The council may receive financial and technical support from international organisations or local organisations. To avoid a conflict of interest, it should however not receive money or other support directly from individual pharmaceutical companies or others having an obvious interest in selling of medicines.

### **Experience from other regions:**

The five Nordic Countries (Denmark, Norway, Sweden, Finland and Iceland) formed a similar council, The Nordic Council on Medicines (NLN) in 1975. This was a great success and supported the development of modern medicines regulations in these countries. Actually, the work of NLN was recognized in many more countries, and led to significant developments in the EU. Before the time when all Nordic Countries became members or associated with EU procedures, the facilitation of training and sharing of workload was very significant. The five small countries taken together could achieve a lot more that if they had worked on individual bases. The principle of voluntary cooperation may sound weak, but in reality it was very well functioning. The Ministers of Health provided the forum, and the professionals took all the opportunities to work together. For obvious reasons, the Nordic Council was closed down in 2002, since all countries is now participating in the EU procedures coordinated by the European Medicines Agency in London.

The three Baltic States (Estonia, Latvia and Lithuania) also formed such a forum in 1992 to foster cooperation in that region. It was very much a copy of the Nordic Council and actually a lot of activities were joined together between the two regions.

For very small investments, this gave great benefits in terms of better regulatory service and saving of resources among the regulatory agencies.

### **Important expected benefits:**

- Improved capacity and quality in national medicines regulation
- Internationally harmonized regulatory decisions
- Saving of costs in participating countries
- Saving time and costs for pharmaceutical industry
- Facilitation of harmonisation with EU-rules and international guidelines

- International recognition of medicinal products manufactured in the participating countries

**Conclusion:**

A fully voluntary scheme for cooperation on medicines regulation in the region is recommended; where each individual participating agency or competent authority is free to choose what activities they will enter into. The idea of establishing the Council on Medicines for South East Europe is very much supported by WHO.

It is recommended that Ministers of Health in the region are taking the necessary steps for further assessment and development of this idea.

## Annex 2

# CONFERENCE PROGRAMME

### Sunday, 26 February

- 18:00      **Reception**  
19:00      **Welcome drink**

### Monday, 27th February

- 9.00-9.30      **Introduction and welcome**      Minister of Civil Affairs, Bosnia and Herzegovina  
Minister of Health, Federation of Bosnia and Herzegovina  
Minister of Health, Republika Srpska  
Head of Health Department, District Brcko  
Representative of European Union  
Representative of World Health Organisation
- 9.30-9.50      **Introduction to the topics of the conference**  
Mr Haris Hajrulahovic, WHO Liaison Officer, Country Office Bosnia and Herzegovina  
Mr Kees de Joncheere, WHO Regional Office for Europe  
*Points: The EU-funded project in BiH*  
*Major improvements achieved of the regulatory framework in the region*  
*Importance of international cooperation in the region*

### **Session 1: MEDICINE POLICIES**

**Chairperson:** Dr Vesna Koblar, Slovenia

- 9:50-10:10      **National Medicines Policy**  
Dr Ljiljana Stojanovic, Serbia and Montenegro
- 10:10-11:00      **Discussion** –sharing experiences on national medicines policies
- 11:00-11:20      **Coffee break**

### **Session 2: REGULATION ON MEDICINES**

- 11:20-11:40      **Overview of a Multi Country Study of Medicines Regulation**  
Mr Ola Westbye, WHO Regional Office for Europe
- 11:40-12:00      **Recent developments in Hungarian legislation and regulatory practice**  
Dr Czaba Haraszti, Hungary
- 12:00-12:20      **National experiences in harmonisation of laws and regulations with the EU-rules**  
Dr Vesna Koblar, Slovenia
- 12:20-12:40      **Experiences in establishing a Medicines Regulatory Agency**  
Dr Sinisa Tomic, Croatia
- 13:10-14:30      **Lunch**

### Session 3: INSPECTION OF MANUFACTURERS AND WHOLESALERS (GMP)

**Chairperson:** Dr Aida Mehmedagic, Bosnia and Herzegovina

14:30-14:50 **Overview of pharmaceutical inspection in South Eastern European countries**

Mr Slobodan Lucic, Bosnia and Herzegovina

14:50-15:20 **The Role of PIC/S in International Harmonisation**

Dr Hans Smallembroek, The Netherlands

15:20-15:40 **Discussion**

*Points: Recognition, training, licensing, cooperation, GMP- training for industries*

15:40-16:00 **Coffee break**

### Session 4: POST MARKETING SURVEILLANCE

16:00-16:20 **Services offered by the WHO International Pharmacovigilance Programme**

Mr Sten Olsson, WHO Collaborating Centre for International Drug Monitoring (UMC)

16:20-16:40 **Discussion**

*Points: Functioning of national centres in the region*

*How to improve relevant reporting*

*Communication with doctors*

*How to achieve correct use with less adverse reactions*

16:40-17:00 **Quality survey of medicines in Bosnia and Herzegovina**

Dr Aida Mehmedagic, Bosnia and Herzegovina

17:00-17:20 **The European Network of Official Medicines Control Laboratories**

Mr Richard Wanko, France

17:20-17:30 **Discussion**

*Points: International recognition, OMCL network, Pharmacopoeia*

*Control of products, requiring special equipment and trained staff*

*Regional cooperation – exchange of samples*

*Regional warning system in case of substandard test results*

*Harmonized administrative decisions in case of problems*

### Session 5: PRICING AND REIMBURSEMENT SCHEMES

17:30-17:50 **Pricing and Reimbursement in European Union**

Dr Claudia Habl, Austria

17:50-18:30 **Discussion**

*Points: Tendering*

*Comparative prices*

*Reference prices*

*Reimbursement criteria*

*Positive lists /negative lists*

18:30 **First Day Close**

19:30 **Official Conference Dinner**



Ms Radojka Malbasic, Bosnia and Herzegovina

15:30–16:00 **Discussion**

*Points: Training of pharmacists and inspectors*

*Licensing*

*Ownership*

*Conflict of commercial and professional interest*

*Pharmacies as first level health care providers*

16:00–16:20 **Coffee break**

### **Session 3: REGIONAL COOPERATION**

#### **THE ESTABLISHMENT OF THE "COUNCIL ON MEDICINES FOR SOUTH EASTERN EUROPEAN COUNTRIES**

**Chairpersons:** Dr Sinisa Tomic, Croatia

Mr Kees de Joncheere, WHO Regional Office for Europe

16:20–16.35 **Introduction**

Mr Ola Westbye, WHO Regional Office for Europe

Mr Kees de Joncheere, WHO Regional Office for Europe

Notes: Discussion paper

16.35 – 18:00 **Discussion**

All participants

*Points: Organisational structure, governing, form of cooperation, area of cooperation*

*Establishment of a permanent secretariat*

*Type products (bulletin, web-site, conferences, training sessions, etc.)*

*Financing*

*Finding a host country*

*Decision making on the establishment*

18:00–18:20 **Conclusions of the Conference**

Mr Kees de Joncheere, WHO Regional Office for Europe

### *Annex 3*

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