

INTERNATIONAL MEETING OF WORLD PHARMACOPOEIAS**Geneva, 29 February–2 March 2012****MEETING REPORT****Introduction**

The international meeting of world pharmacopoeias was opened by Dr Carissa F. Etienne, Assistant Director-General of the Health Systems and Services Cluster of the World Health Organization (WHO). Dr Etienne welcomed all delegations from the national and regional pharmacopoeias. The answer to WHO's call and invitation for this meeting had been great; from the existing world pharmacopoeias (Index of pharmacopoeias, document QAS/11.453, dated March 2012 – Annex 1) 23 had accepted to be present with seven informing WHO that they were unable to attend, i.e. People's Republic of China, Estonia, Hungary, Iceland, Islamic Republic of Iran, Turkey and Viet Nam.

Dr Etienne emphasized that the WHO Director-General's list of priorities included access to safe quality medicines and that the efforts and discussions during the meeting would, therefore, be an important milestone for WHO and its Member States in the goal towards global access to efficacious quality medicines for patients. One aim would be to provide new ideas and strategies for the future to WHO's Member States.

Dr Lembit Rägo, Team Coordinator, Quality & Safety: Medicines, highlighted that we are living in a changing world, that dynamics and changes are occurring in pharmaceuticals all around the world. Medicines regulation increasingly relies on networking and collaboration among the regulators.

Objectives of the meeting

The outcome and recommendations will be presented to the WHO Expert Committee on Specifications for Pharmaceutical Preparations which advises the Director-General and WHO's Member States on future perspectives and strategic approaches in relation to pharmacopoeias. Furthermore, the outcome will be used as a basis for a public international meeting which is being organized in collaboration with the International Pharmaceutical Federation (FIP) and to which pharmacopoeial bodies and interested parties, especially users from the pharmaceutical industry, control laboratories, universities and the regulatory field, will be invited to participate.

Background

Harmonization efforts in the area of pharmacopoeias started more than a century ago. WHO was mandated with its Secretariat in 1948. This led to the creation of the International Pharmacopoeia.

A first initiative to reopen the discussion on international harmonization of quality control specifications on a global scale was taken in a side meeting of the 10th International Conference of Drug Regulatory Authorities (ICDRA) entitled "Pharmacopoeial Specifications – need for a Worldwide Approach?" in Hong Kong on 24 June 2002, i.e. 10 years ago. This further led to the discussions among regulators during the 11th ICDRA meeting held in Madrid in 2004. Several points discussed in these two meetings and especially the recommendations were used as a background document for this meeting.

This meeting was chaired by Professor A. Nicolas, Directeur des Laboratoires et des Contrôles, Agence française de sécurité sanitaire des produits de santé, France and co-chaired by Professor G. Pianetti, President, Brazilian Pharmacopoeia, Brazil, Dr G.N. Singh, Drugs Controller General, and Secretary-cum Scientific Director, Central Indian

Laboratory, India, and Mr N. Yasuda, International Planning Director, Minister's Secretariat, Ministry of Health, Labour and Welfare, Japan.

The delegations included representatives from international, regional and national pharmacopoeias. The list of participants is attached as Annex 2.

Summary of discussions

The first day was devoted to the presentations of the various world pharmacopoeias. The questions listed in Annex 3 were addressed. The participating pharmacopoeias outlined inter alia their strategies for the future and underlined particularly the need for harmonization among pharmacopoeias. The presentations would be made available online on the WHO Medicines web site together with a summary report.

The role of the pharmacopoeia in a changing world – exchange of views on how to react and which actions are taken by each pharmacopoeia

Globalization induces the existence of different sources of active pharmaceutical substances (APIs), excipients, intermediates, bulk and finished pharmaceutical products (FPPs) on the market. New methods have to be introduced in the pharmacopoeias, considering characterization and control of different solid states of the compounds, impurities and new pharmaceutical forms. Considerations need also to be given to the expansion of the scope to include new biological medicines, herbal medicines,¹ such as traditional Chinese, Ayurvedic and homeopathic medicines, and possible adulteration and falsification. Latest trends include the need for increased transparency to favour harmonization between the pharmacopoeias to provide further assurance for patients'

¹ Herbal medicines include *herbs, herbal materials, herbal preparations* and *finished herbal products*. In some countries herbal medicines may contain, by tradition, natural organic or inorganic active ingredients that are not of plant origin (e.g. animal and mineral materials); reference: WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems, World Health Organization, Geneva, 2004.

safety. Exchange of information on the published and draft monographs, work plan and available reference standards can be facilitated by using a communication platform hosted by WHO. One way to achieve this could be to create a repository of web links with enabled possibility to search for items across all links.

Infrastructure and resources – are we prepared to face the new challenges?

Pharmacopoeias are responding to the new challenges by developing scientific work in these areas. However, nowadays even well-resourced pharmacopoeias face challenges to fulfil the increasing workload related to their mandates. Effective networking and harmonization will be key for the future to cope with the new challenges. Some pharmacopoeias enable free access to their publications. This public information-sharing was discussed but for some this was not compatible with their financing model.

Harmonization efforts and development of pharmacopoeial texts: globally, regionally, interregionally – opportunities for work-sharing

Generally it was agreed that prospective actions are easier than retrospective harmonization. Experience from various pharmacopoeial harmonization efforts were shared, including those carried out under the pharmacopoeial discussion group (PDG) and the Mercado Común del Sur (MERCOSUR). New platforms for the pharmacopoeial harmonization process should be identified and open to all pharmacopoeias wishing to participate. Aims and objectives should be defined, should this be agreed.

When discussing international harmonization it needs to be kept in mind that each pharmacopoeia operates within a national or regional legal framework.

The possibility of using a new collection of "performance-based monographs", free for use by any interested party, including pharmacopoeias, proposed as a means to increase understanding of how to harmonize pharmacopoeial monographs, was discussed, but there was no consensus at this meeting to use it.

Addressing new challenges of medical² products with unexpected impurities and added substances (unintentional, adulterated or falsified)

The creation of a common general chapter to act as a toolbox with rapid screening methods using various modern technologies was considered to complement pharmacopoeial tests. Delegates supported this initiative.

Future vision of the pharmacopoeias

The delegates shared their different strategies and vision of the future.

The ideas and various strategies have been referred to under the different agenda items and taken up in the above parts of the report.

Conclusions

New ideas and strategies for the future were reviewed. The main emerging suggestion was the development of "Good Pharmacopoeial Practices" to favour prospective harmonization, which procedure WHO could facilitate. The outcome could be discussed at a future joint international meeting of world pharmacopoeias by the latters' active participation.

An initial drafting group was formed during the meeting and is composed of: Argentina, Brazil, European Pharmacopoeia, India, Japan, Mexico, Russian Federation, Ukraine, United States Pharmacopoeia, with editorial assistance being provided by the United Kingdom. The whole process is intended to be open to all pharmacopoeias. It was agreed to draft such a document under the auspices of the WHO Expert Committee on Specifications for Pharmaceutical Preparations.

² "Medical products" was the term agreed at the first Working Group of WHO Member States on substandard/spurious/false-labelled/falsified/counterfeit medical products to refer to medicines, vaccines and in vitro diagnostics (and in the future may include medical devices).

The delegates considered the important role of The International Pharmacopoeia for public health and wished to express their support for strengthening these activities.

The outcome of this meeting will be shared with the users and stakeholders of the pharmacopoeias, including regulators, quality control laboratories and manufacturers.

A public meeting will be held in collaboration with FIP in conjunction with its Centennial meeting on 7-8 October 2012. Another opportunity for discussion will be at the next ICDRA meeting; the public pre-ICDRA is 21-22 October 2012 and ICDRA 23-26 October in Estonia.

Participants suggested joining forces with similar activities and hold international meetings with world pharmacopoeias at a regular interval. India has proposed to host the next meeting.

ANNEX 1

Please see the Index of pharmacopoeias (document QAS/11.453) for the existing world pharmacopoeias, as notified to WHO:

http://www.who.int/medicines/publications/pharmacopoeia/INDEX-OF-PHARMACOPOEIAS_16032012.pdf

ANNEX 2



INTERNATIONAL MEETING OF WORLD PHARMACOPOEIAS

29 February–2 March 2012

WHO, Geneva, Executive Board Room

LIST OF PARTICIPANTS

Argentinian Pharmacopoeia

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Technical Secretary

Farmacopea Argentina

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Ciudad Autónoma de Buenos Aires

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Co-chair

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Council of Europe

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Professeur Alain NICOLAS and Chair to the meeting

Directeur des Laboratoires et des Contrôles (DLC)

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Saint-Denis Cedex, France

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Dr Jochen Norwig

Indian Pharmacopoeia

Dr G. N. Singh

Co-chair

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Mr Naoyuki Yasuda

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International Planning Director
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Head, Department of Kazakh National Medical University

Professor Tulegenova Ardak

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Portuguese Pharmacopoeia

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Chair of the Portuguese Pharmacopoeia Commission

Dr Maria João Portela

Directora da Direcção de Comprovação da Qualidade
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Specialist of Centre of the Pharmacopoeia and
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Dr Herbert Schmidt, Medicines Quality Assurance Programme

Mr Dušan Jasovský, Intern, Medicines Quality Assurance Programme

Dr Jethro R.H. Kuwana, Prequalification of Medicines Programme

Dr Ian Thrussell, Head of Inspections, Prequalification of Medicines Programme

Dr Raffaella Balocco, Manager, International Nonproprietary Name Programme

Dr Samvel Azatyan, Manager, Medicines Regulatory Support Programme

Department for Health Systems Policies and Workforce

Ms Yukiko Maruyama, Traditional Medicine

ANNEX 3

Questions to pharmacopoeias

- 1. Name of pharmacopoeia**
- 2. Pharmacopoeia referred to in national/regional legislations**
if yes, which
- 3. National/regional legislation includes reference to other**
 - national pharmacopoeias(s)
if yes, which
 - regional pharmacopoeias(s)
if yes, which
 - international pharmacopoeias(s)
if yes, which
- 4. Publication of latest edition**
- 5. Update frequency**
 - annually
 - biannually
 - other, please specify
- 6. For which products does the pharmacopoeia provide specifications?**
APIs, dosage forms, herbal products, biologicals, traditional medicines, etc
(please specify)

7. Number of texts included in the pharmacopoeia

- monographs for APIs
- monographs for finished dosage forms
- monographs for biologicals
- general monographs
- supplementary texts

8. Collaboration with and/or being part of a (different) national/regional pharmacopoeia

if yes, which

9. Publication of harmonized pharmacopoeial texts within the pharmacopoeia

if yes, which pharmacopoeia

if yes, which type

if yes, how many

10. Interaction with stakeholders, including regulators

if yes, which

11. Strategy for the future

if yes, which
