

LMCS ACTIVITY REPORT 2005

Here is presented the activity report concerning the year 2005 on the following activities:

- Newsletter
- Spring Meeting
- Multinational Collaborative Study
- Proficiency Testing Programme
- Studies on Counterfeit Medicines
- LMCS website
- FIP Annual congress
- Membership

Newsletter

The goal of issue 4 newsletters was accomplished in 2005. The newsletters were sent to all the effective members of FIP with updated information concerning the section activities and news about technical and professional matters related with medicines and methodology in pharmaceutical R & D.

In the 4th number of the Newsletter a new section was included aiming to give voice to all members to express their feelings towards matters that worry their country.

It was made an invitation to all members to send articles about issues and worries that they would like to share to all colleagues.

Spring Meeting

Due to some unexpected difficulties the Spring Meeting, that was going to be held in Moscow, had to be postponed.

The preparatives for the Spring Meeting 2006, that will take place in Cape Verde, were initiated. The preliminary programme is available in the Website and was published in the last Newsletter of 2005. The invitations to speakers are being done. We have started to collect registrations for the Meeting.

We plan to use FIP means of communication to promote this event.

Multinational Collaborative Studies

It was published on vol. 19, of the International Pharmacy Journal, the results concerning the Multinational Collaborative Study of 2004/2005.

Authors: Ascensão Farinha, António Bica

Name of the article - "Inaccurate dosage; Results from the FIP-LCMS collaborative study".

International Pharmacy Journal, vol.19, N°1

Proficiency Testing Programme (PTP)

The results of the 7th round LMCS PTP were presented in the Business Meeting of Cairo. The programme covered:

1. The determination of the content of prednisolone sodium phosphate oral solution 1.34 mg/ml
2. The pH measurement of buffer solution M
3. The check of the absorption spectrophotometer according to the procedures of the European Pharmacopeia

In total 43 laboratories from 37 different countries participated in the round. The distribution of the origin of the participating countries is as follows:

Europe: 16 countries

Asia: 12 countries

Africa: 4 countries

America (n+s): 4 countries

Pacific :1 country

The PTP for 2006 was planned and the samples will be sent to all laboratories during January of 2006. The results will be compiled until the 24th of March.

Studies on Counterfeit Medicines

LMCS planned, for 2005/2006, two projects concerning the problem of counterfeit medicines:

- **Project A** - Quality assessment of drug products distributed through the authorized channels in developing countries;
- **Project B** - Detection of counterfeit products (Viagra and Xenical) distributed through alternative distribution channels

Project A

The objective of this study is to evaluate the quality and to detect cases of counterfeiting of drug products containing active substances with a high therapeutic value on the countries included, providing valuable data to accurately address the counterfeit issue.

To achieve this objective it's our intention to develop simple analytical methods that can be easily transposed for the reality of the developing countries.

At the end of the study we would like to be able to analyse the circuit taken by the counterfeit products and to detect how it was possible for these products to enter the distribution channels.

We will extend this study to all African countries where Portuguese is the official language.

LEF has invited several entities, from Angola, Brazil, Cape Verde, Guinea Bissau, Mozambique and S. Tomé e Príncipe, to help in the selection of the active substances and in order to provide the products sampling.

After a discussion with all the intervenients in the project, three important therapeutic groups were chosen:

- Artesunato (antimalarial)
- Cotrimoxazol (antibiotic)
- zidovudine (antiretroviral)

The study protocol was made and the products are arriving to Portugal. The results will be available for presentation in the Business Meeting within the FIP Congress in Brazil.

Project B

It is our objective to evaluate the quality of medicines distributed through the alternative channels (internet, gymnasiums, etc) detecting possible cases of counterfeiting. In order to represent this market we chose the products Viagra and Xenical. All members of LMCS will be invited to participate in the sampling of the products which will be analysed in some laboratories.

We are contacting the local AIM holders (Pfizer and Roche) inviting them to participate and asking for their help in the development of analytical methods.

The project was postponed due to the associated complexity, which requires further discussion.

FIP Annual Congress – LMCS Symposia

Cairo

Our section together with SIG Bioavailability/Bioequivalence, SIG Quality of Pharmaceuticals, Industrial Pharmacy Section has organized a symposium. Under the theme_“DISSOLUTION TESTING – A PIVOTAL TOOL FOR DEVELOPMENT AND QUALITY OF DRUGS, Cairo, 2005

The symposia had a great affluence and the issues debated were participated.

Brazil

A two half-day symposium on measures to combat the counterfeiting of medicines across the globe to fit the Congress theme of “Bringing innovation into practice”.

A joint Board of Pharmacy Practice/Board of Pharmaceutical Sciences symposium organised by the Industrial Pharmacy Section, Laboratory and Medicines Control Services Section and the Quality Pharmaceuticals Special Interest Group.

The programme was published in the LMCS Newsletters and is available in the website.

We Plan to use the FIP means of communication to promote this event.

LMCS Website

The section updated the website twice, in April and in December. In April the modifications concerned the announcement of new activities for 2006. In December the content of the website was reviewed, maintaining the current layout. The objective of this change was to promote the consult of useful information in the website and it's visiting from members and non-members.

Simultaneously, we are preparing to include more information in some areas of the website, such as the Multinational Studies and the Proficiency Testing Programme, with more data about past studies and their conclusions.

We also would like to promote the interaction between members, through a web forum, which, with weekly themes, would create an attraction to our section of the site and would make available to the others the ideas and opinions of all members. Such web forum was impossible to create, as the available tools of FIP couldn't respond to our intension.

Instead, it was suggested that we turn this web forum into an e-mail forum, with a controlled environment of incoming e-mails and with a weekly summary of all the expressed opinions posted in the site.

This is the proposal we have on the table and hope to fulfil in 2006.

Membership

The aim of the section for 2005, to promote the Section activities using the means of communication available in FIP will be prosecuted for 2006. In 2005, in order to increase the number of members, LMCS has used the e-mail to communicate with members, updated the website and published an article on the International Pharmacy Journal.

The section has maintained the number of members.

Ascensão Ribeiro Farinha
LMCS Secretary

Lisbon, 27th January 2006