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Pharmaceutical Forum of the Americas

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66TH CONGRESS OF PHARMACY AND PHARMACEUTICAL SCIENCES

This international Congress took place from August 25th to 31st, under the slogan "Bringing Innovations into Patient Care". It is the most important event for the pharmaceutical profession and sciences. This edition was the first time that the annual Congress is held in Latin America. The audience was integrated by over 2100 pharmacists, pharmaceutical care experts, government authorities, researchers and health professionals from 89 countries.
The Opening Ceremony counted with the presence of recognized authorities both in the National and International level, including the Minister of Health of Brazil, Dr. Agenor Álvarez, the President of the Federal Council of Brazil, Dr. Jaldo de Souza Santos and the past president of FIP, Jean Parrot.
The Congress included numerous activities, covering all the aspects of Pharmacy. About 50 programs were developed during the seven days of the event, in different modalities as round tables, workshops, forums, meetings and panels.

FIP approved and launched three statements during its Council meeting:

- FIP Statement of Policy on the Role of the Pharmacist in the Prevention and Treatment of Chronic Disease (Link to PDF)
- FIP Statement of Professional Standards on the Role of the Pharmacist in Crisis Management: including Manmade and Natural Disasters and Pandemics (link to PDF)
- FIP Statement of Policy on the Role of the Pharmacist in Pharmacovigilance (link to PDF)

Find more information about the congress in: http://www.fip.org and http://www.cff.org.br

ELECTIONS IN FIP

On August 26th, during the 66th FIP Congress in Salvador Bahía, the Council of the International Pharmaceutical Federation elected Dr. Kamal K. Midha as the new President of FIP. He will perform in this position of the federation for the 2006-2010 term.

DR. MIRTA ROSES DISCUSSED THE HEALTH AGENDA IN THE WORLD CONGRESS OF PUBLIC HEALTH IN BRAZIL

The Director of the Pan American Health Organization (PAHO), Dr. Mirta Roses, participated in two important international meetings held in Brazil: The 11th World Congress on Public Health and the 8th Brazilian Congress on Collective Health. The main objective of these events was to discuss the strengthening and development of Public Health. These meetings counted with the presence of the president of Brazil, Luiz Inácio Lula da Silva, and other Brazilian health authorities, and gathered over 8000 experts in the different fields of health.
Dr. Mirta Roses discussed in this occasion the approach that the new health agenda will adopt. She commented that the countries of the Region are very interested in the formulation of a common health framework, which will be called "The Health Agenda of the Americas, 2008-2017". The new agenda will serve the health organizations as a guide to develop future strategic health plans, and will be oriented to achieve concrete improvements in the field. Some of the topics are the regional perspective, the compilation, analysis and development of declarations and initiatives, mobilization of resources and political will.
Source:
http://www.paho.org/English/DD/PIN/pr060822.htm

MARGARET CHAN IS THE NEW DIRECTOR OF WHO

Dr. Chan, from China, was elected on November 9th as the new director of WHO. Dr. Nordström will remain as director until Dr. Chan assumes her new position. Under her leadership were controlled the outbreaks of H5N1 in 1997 and SARS in 2003.
More information: www.who.org

FDA APPROVED THE OTC SALE OF THE "MORNING AFTER PILL"

The Food and Drug Administration (FDA) approved this emergency contraception medicine as an over-the-counter for women aged 18 and older. This product will remain as a prescription-only product for women under 18.
The pill contains the same active principle that some birth control pills, Levonorgestrel, but in a higher dose and a different dossing regimen. It acts interfering with ovulation and preventing the implantation of fertilized eggs. The FDA's Plan B information page:
http://www.fda.gov/cder/drug/infopage/planB

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MEDICALIZATION OF PREVENTION: QUESTIONABLE EVIDENCE ABOUT THE USE OF MEDICINES IN THE PREVENTION OF DIABETES

Rosiglitazone is an antidiabetic drug of the thiazolidinedione family that increases the sensitivity of the body to insulin. This drug is currently approved for the treatment of type 2 diabetes.

On September 15th, in the frame of the Congress of the European Association for the Study of Diabetes, a Canadian research team presented the results of The Diabetes Reduction Assessment with Ramipril and Rosiglitazone Medications (DREAM) trial. This study suggests that Rosiglitazone would decrease in around two-thirds the risk of developing type 2 diabetes in high risk individuals. The other arm of the study that tested the ACE inhibitor Ramipril, despite previous trials, did not show favorable outcomes.

This three years long study counted with nearly 5,300 patients with high risk of developing type 2 diabetes. They were randomized between the intervention group, that received 8 milligrams of Rosiglitazone, and the control group, that received placebo. All the patients from both groups were encouraged to adopt a healthy life style.

The results show that Rosiglitazone reduced between 60 and 70 percent the risk of developing type 2 diabetes compared to placebo. The 10.6 percent of those prescribed with Rosiglitazone developed type 2 diabetes, compared to 25 percent in the control group.

On the other hand, an increase in the prevalence of cardiac failure events was observed: 14 with Rosiglitazone against 2 with placebo.

In the world, there are about 300 million people considered to have pre-diabetes. This trial would open a multi millionaire market for GlaxoSmithKline.

Recently the follow up of an intensive lifestyle intervention in high-risk persons was published. This study presents a significant reduction in the relative risk of developing type 2 Diabetes, and showed not only that that these interventions are effective, but also durable in time after the cessation of the program **(*Lancet. 2006 Nov 11;368(9548):1673-)***. An extensive article on this study will we presented in the next bulletin.

Public Citizen, an American non-governmental organization, has been denouncing for years the inadequate use of Rosiglitazone based on the lack of necessary evidence to maintain its prescription. They argument that its safety and effectiveness are low compared to other antidiabetic drugs in the market.

Some of the adverse events of Rosiglitazone are weight gain, hepatotoxicity, anaemia, fluid retention, dyslipidaemia, among others.

Presently, as shown in a study with over 13,000 patients, Glitazones are being inappropriately prescribed to individuals with clear contraindications as congestive heart failure ***(Metformin and thiazolidinedione use in Medicare patients with heart failure.* Journal of the American Medical Association *Jul 2, 2003; 290: 81 – 85)***. This is a topic to be taken into account considering the increase in prescriptions that the medicines containing Rosiglitazone would experience.

Sources

EMEA's full EPAR: http://www.emea.eu.int/humandocs/Humans/EPAR/Avandia/Avandia.htm

Public Citizen http://www.citizen.org/; Medline Plus http://www.nlm.nih.gov/medlineplus/news/l

The DREAM trial has been published in the online edition of The Lancet on September 15th.

POSSIBLE RELATION BETWEEN CONTRACEPTIVE PATCHES AND VENOUS THROMBOEMBOLISM EVENTS

Two research groups conducted two separate studies to evaluate the risk of venous thromboembolism in women using transdermal contraceptive patches containing 6 mg of norelgestromin and 0.75 mg of ethinyl estradiol. The studies compared this product with common oral contraceptive pills containing 35 mg of ethinyl estradiol and norgestimate.

One study did not find any significant increase in the risk of non-fatal venous thromboembolism (VTE) while the other study associated the use of the contraceptive patch with a two-fold increase in the risk of VTE.

FDA warned last year about the increase in exposure to high levels of estrogen present with this product. Actually FDA is updating the label.

Source: http://www.fda.gov/medwatch/safety/2006/safety06.htm#Evra

ALARMING NEWS…

The Supreme Court of Justice of Mexico approved the sale of non under prescription non OTC medicines in ***vending machines***. These can be placed in any public space. The Supreme court alleged, among other reasons, that the law that prohibited this was interfering with the right of access to medicines.

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