NEWS
Pharmaceutical Forum of the Americas

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RUBELLA ELMINATION GOAL SETTLED FOR THE YEAR 2010

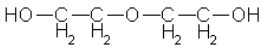
In the last days of September the Ministers of Health subscribed to the compromise of eliminating Rubella and the Congenital Rubella Syndrome for the year 2010. In a document developed by PAHO/WHO the Ministers also compromised to introduce new generation vaccines for other priority diseases and to reach the 95% vaccination coverage in the entire Region for the principal vaccines. The working paper also highlights the need of keeping the 95% coverage of the measles vaccine.

The document was presented by Dr. Gina Tambini, the director of the Family and Community Health Area of PAHO. Dr. Tambini emphasised the relevance that the Vaccination Week in the Americas is acquiring, and remembered some of the milestones of vaccination in America, as the eradication of poliomyelitis, measles and neonatal tetanus, the control of yellow fever and the introduction of the Rubella and the pentavalent vaccines. She also explained some of the unresolved issues of the Region, as the lack of high equity coverage.

The ministers requested support to the Director of PAHO for the implementation of the necessary initiatives to reach the 2010 goal.

Source:
http://www.paho.org/english/dd/pin/pr060929.htm

DEATHS IN PANAMA CAUSED BY DIETHYLENE GLYCOL



The National System of Epidemiology Surveillance of Panama detected in September an unusual increase in the number of cases presenting with the syndrome of acute renal failure.

The cause was the presence of diethylene glycol in a sugar free cough syrup. The toxic was found in barrels of glycerine used for the production of four different medicinal products, including the cough syrup. Up to November 27th, this toxic solvent had caused the death of 45 Panamanians.

Source: WHO pharmaceutical Newsletter, N5 2006
http://www.minsa.gob.pa/

LATIN AMERICA AND THE CARIBBEAN SEEKS TO STOP DEATHS CAUSED BY PNEUMOCOCCAL DISEASE

On December 15th took place the 2nd Regional Pneumococcal Symposium in San Pablo, Brazil. In this frame, the health leaders of Latin America and the Caribbean made a call for action to promote the use in children of modern vaccines against this disease.

Actually, a Pneumococcal vaccine covering 7 serotypes of the bacteria is available. It is widely used in EEUU, where it reduced the incidence of Pneumococcal disease by 80% in children, and lowered the transmission to the elderly. However, due to its high cost, only Mexico and Brazil could partially implement this vaccine in the Region, and only in part of their high risk population.

The initiative that took shape in this Symposium seeks to promote the diffusion of these vaccines. PAHO and its Revolving fund were considered essentials in this work plan, and were requested to work with governments, agencies and manufacturers to facilitate the achievement of the vision of a wide vaccination in the Region.

A study investigating the impact of Pneumococcal disease in Latin America and the Caribbean was published recently. The study was based in a bibliographic revision of all the related articles published between 1999 and 2006, plus contacting numerous researchers from all Latin America.

The authors found that Pneumococcal disease kills 18,000 children a year. The study also concludes that a high scale vaccination could halve the number of cases and deaths related to Pneumococcal bacteria.

Sources:
http://www.paho.org/Spanish/DD/PIN/ps061215.htm
http://www.paho.org/Spanish/DD/PIN/ps061213.htm

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RESOUNDING SUCCESS OF PERU IN RUBEOLA VACCINATION CAMPAIGN

The Pan American Health Organization certificated on January 11th the achievement of Peru of the goals set for "Vaccination Campaign for the Eradication of Rubella and the Congenital Rubella Syndrome".
The Campaign reached over twenty million Peruvians thanks to the effort of the Ministry of Health, the vaccinators and the society in general.
The Minister announced a Hepatitis B Vaccination Campaign for the year 2007, consisting of three free doses of this vaccines to an estimated of fourteen million Peruvians between two and nineteen year of age. Hepatitis B is an endemic disease in Peru.

Source:
http://www.paho.org/Spanish/DD/PIN/ps070111.htm

NEW WEB SITE FOR CANADA'S ACCESS TO MEDICINES REGIME

The Health System of Canada launched a web site to facilitate the access to information and procedures of the Canada's Access to Medicines Regime. It consists in framework for developing countries to import less expensive generic versions of patented drugs and medical devices.
This initiative is based on the authorization of the World Trade Organization to some of its member states to export vital medicines and devices to some selected countries that have little of no capacity to manufacture them, especially in regard with HIV/AIDS, tuberculosis and malaria medicines.
The products imported in this channel must meet the same requirements of safety, quality and effectiveness than the products commercialized in Canada.

Visit the web site:
http://camr-rcam.hc-sc.gc.ca/intro/index_e.html

NEW DIAGNOSIS TEST FOR HIV

This new test is the first assay approved for the detection of HIV-1 virus, the principal etiologic agent of AIDS. The advantage of this test is that it can detect the early HIV-1 infection, even before the presence of antibodies to HIV-1. The test is designed to detect the genetic material of the virus. It is a potential tool for Public Health for the early detection and confirmation of HIV-1 infection.

Source:
http://www.fda.gov/bbs/topics/NEWS/2006/NEW01479.html

REMARKABLE COMMENT IN THE NEW ENGLAND JOURNAL OF MEDICINE

A large observational study determined that the use of the antifibrinolytic drug aprotinin, used to reduce postoperative bleeding in patients undergoing cardiac surgery, increases the incidence of certain complications, as cardiovascular events and postoperative renal failure.
In view of the conclusions of this study the FDA reviewed the safety of this drug on September 21st but decided not to add new, stronger warnings. Later on, it became of public knowledge that the manufacturer had funded a private study that reached the same conclusions of the previous study, but did not present the results to the FDA, even though these were available before the safety review meeting.
Finally, the FDA changed the safety information in December. The updated label includes a warning about the risk of kidney damage and states that this medicine should only be used in patients with high risk of blood loss during cardiac surgery.
This company has already been accused of a similar manoeuvre in regard with unfavourable information about cerivastatin. This irregularity rings a bell, because of its similarity with the Vioxx case, when Merck hid information about its cardiovascular safety.

Source: NEJM **Volume 355:2169-2171**
http://www.fda.gov/cder/drug/infopage/aprotinin/default.htm

67th International Congress of FIP
'From Anecdote to Evidence: Pharmacists Helping Patients Make the Best Use of Medicines'

Beijing, China, 31 August - 6 September 2007

MEDICALIZATION OF PREVENTION II: THE CONCLUSIVE IMPACT OF LIFE-STYLE MODIFICATIONS

In the last number we criticized medicalization in view of the results of the DREAM trial.
In November 11th The Lancet published the second phase of a study about a life-style intervention in patients with high risk of developing type 2 Diabetes. This second stage consisted in a 3-years follow-up of the patients that did not develop Diabetes during the first 4 years of the study. In this period the intervention ceased, so that any of the two groups received any kind of counselling. The objective of the follow-up was to determinate the magnitude in which the previously introduced beneficial modifications in life-style persist over time, and their impact on the incidence of type 2 Diabetes.
In the first stage, patients with impaired glucose tolerance were randomised between an intensive life-style intervention and a control group. After four years the incidence of type 2 Diabetes in the intervention group was significantly smaller than the incidence in the control group.
The total study, counting the intervention and the follow-up period (7 years), found a 43% reduction in the incidence of type 2 Diabetes. This risk reduction was related to the achievement of beneficial changes as weight loss, increased physical activity and improved food habits.
The post-intervention follow up found that, even after active counselling finished, beneficial life style modifications persisted. This fact is reflected in the 36% relative risk reduction found in this period.

Source: ***Sustained reduction in the incidence of type 2 diabetes by lifestyle intervention: follow-up of the Finnish Diabetes Prevention Study. Lancet 2006; 368: 1673–79***

NSAIDs: SAFETY ACCORDING TO THE EMEA

The European Medicines Agency (EMEA), based in new evidence, updated their review on the safety of NSAID.
The Committee for Medicinal Products for Human Use (CHMP) found a small increase in the risk of thrombotic events for non-selective NSAIDs, but considered that the overall risk-benefit relation remains favourable, as long as they are used in their authorized conditions.
These are the conclusions reached by the CHMP on each reviewed NSAID:

- **Coxibs**: The new data confirm the increase in risk of cardiovascular events.
- **Diclofenac**: The 150 mg/day dose has a similar risk as some coxibs.
- **Ibuprofen**: the 2.400 mg/day dose is associated with a slight increase in risk of thrombotic events. The analgesic dose of 1200 mg/day has not shown the same effect than the higher dose.
- **Naproxen**: The 1.000 mg/day dose shows a small decrease in risk compared to coxibs, but this cannot be assumed as a protective effect. This dose shows an increase in gastrointestinal adverse effects.

Other three NSAIDs were object of further investigation in regard with their serious gastrointestinal effects. The risk-benefit of **ketorolac** and **ketoprofen** was estimated positive, within their strict conditions of use. **Piroxicam** showed an unfavourable profile of cutaneous and gastrointestinal adverse effects compared to other available NSAIDs; a complete review on this drug is being carried out.

Official releases:
http://www.emea.eu.int/pdfs/general/direct/pr/41313606.pdf
http://www.agemed.es/actividad/alertas/usoHumano/seguridad/

NEW TEST FOR T. CRUZI IN DONORS

The FDA approved a test for the detection of Trypanosoma cruzi (T. cruzi), the casual agent of Chagas disease, in blood, tissue, organs and cell donors. This test works by the detection of T.cruzi antibodies.
In the trials of this diagnostic test, it presented an accuracy of 99 per cent and very few false positives.
This test is not indicated for the diagnosis of Chagas disease.
Source:
http://www.fda.gov/bbs/topics/NEWS/2006/NEW01524.html

67th Congress of the Pharmaceutical Federation of South America
Asunción, Paraguay, 11-14 August 2007

Pharmaceutical Sciences World Congress
3rd World Congress of the Board of Pharmaceutical Sciences of FIP
April 22 - 25, 2007
RAI Congress Centre
Amsterdam, The Netherlands

A GOOD MEASURE OF DIFFICULT APPLICATION

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), an organization representing pharmaceutical industry associations, changed its code of ethics. In this revised version, they prohibit inadequate promotion that could influence prescriber´s decisions, as personal gifts or money.
This measure seems full of good intentions and lines up with the cause of the rational use of medicines; but the extent in which this code will be applied around the world is doubtful.

Source: BMJ 2007;334:64-65 (13 January)
http://www.ifpma.org

STRONGER WARNINGS FOR ADHD MEDICINES

Several agencies, as the FDA and Health Canada, modified the patient information label of medicines for the treatment of Attention Deficit Hyperactivity Disorder. The introduced modifications include potential adverse effects and more extense warnings. The most serious warnings apply to the stimulant-containing medicines, such as methylphenidates and amphetamines. The new warnings include the risk of sudden death, serious cardiovascular adverse events, increase in blood pressure and heart rate, psychiatric complications, slowed growth, seizures and vision problems.
Patients considered for a treatment involving any of these drugs should undergo a physical examination to ensure the absence of heart disease.

Sources: Worst pills best pills Newsletter, Volume 12, Number 11, November 2006
http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/2006/2006_91_e.html

RISK OF HEPATOTOXICITY WITH TELITHROMYCIN

Telithromycin, a ketolide antibiotic derived from Erythromycin, has been related with acute hepatic failure and exacerbation of myasthenia gravis. The adverse reactions include fulminant hepatitis, hepatic necrosis and sudden worsening of the myasthenic symptoms.
The FDA approved a labelling revision in order to include the corresponding safety warnings. The EMEA, besides the warning enforcements, added a contraindication pointing out that Telithromycin must no be administered concomitantly with strong CYP3A4 inhibitors.
Source:
http://www.emea.eu.int/pdfs/human/press/pr/32512806en.pdf; http://w3.icf.uab.es/notibg/

EVIDENCE OF CARDIAC VALVULAR DISEASE WITH PERGOLIDE AND CABERGOLIDE

Two trials studying the effect of dopamine agonists on cardiac valvular disease were published in January.
The researches consisted in a retrospective case-control study and a prevalence study based on echocardiographic diagnosis. Both compared carbegolide, pergolide and non-ergot derived agonists in patients prescribed with these medicines with control patients.
Both studies found an increase in the incidence of cardiac valve regurgitation associated with the use of carbegolide and pergolide. In addition, neither of them found such association with non-ergot derived dopamine agonists.
Source: **N Engl J Med 2007;356:39-46**
N Engl J Med 2007;356:29-38

REVIEW ADVISES NEW WARNINGS FOR DOPAMINE AGONISTS

The Pharmacovigilance Working Party of the European Union emitted a review relating pathological gambling, increased libido and hypersexuality with dopamine agonists. The working party based their conclusion in an exhaustive review of reports and the available literature.
Dopamine agonists are indicated for the restless legs syndrome, endocrine disorders and Parkinson's disease. No reports regarding alpha-dihydroergocryptine or lisuride were found, so these agonists would not include the new warnings.
Source: http://www.mhra.gov.uk