Drug Information Bulletin

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Editorial

Access to health care information especially in resource poor countries is a major impediment to reach quality health care to the people. There are isolated initiatives to reach the health care information to the health care providers and the general people, but there is a huge gap. Dr. Neil Pakenham-Walsh- Coordinator, HIFA2015 – Co-Director, Global Healthcare Information Network has said in an interview that-"*It is tragic that so many children continue to die unnecessarily for want of simple, low-cost interventions that are often locally available. It is even more tragic that many of these children would have been saved if only their mothers, fathers, family caregivers and, indeed, health workers, had basic healthcare knowledge to recognize serious illness requiring urgent, appropriate, life-saving action."*

Recently WHO has modified its Essential Medicine Information Portal. Through this portal Non-WHO publications are being included in the database – these can include journal articles, reports from other organizations and other books where permitted by copyright. Essential medicines documents are now combined with those on other health technologies. WHO partner organizations like - MSH, USAID, World Bank and UNICEF are also making available with their data base.

Now it is possible to find reports of MSF, articles from BMJ, meeting reports of ICDRA, required information from 'Managing Drug Supply" and so on as per available sources.

More such initiative will improve access to health care information and improve the quality of health care system.

Oral fluoroquinolones and retinal detachment reported from Canada

Oral fluoroquinolones are broad-spectrum antibacterial drugs indicated for the treatment of infections caused by susceptible strains of microorganisms (1–5). In Canada, there are five marketed oral fluoroquinolones: ciprofloxacin (first marketed in 1996), levofloxacin (1997), moxifloxacin (2000), norfloxacin (1986), and ofloxacin (1990). The risk of retinal detachment is not described in any of the oral fluoroquinolone Canadian product monographs. Retinal detachment is characterized by a separation of the retina from the underlying tissue in the eye (6). Among the different types of retinal detachment, rhegmatogenous retinal detachment (RRD) is the most common. RRD results from retinal breaks caused by vitreoretinal traction. Risk factors commonly associated with retinal detachment include advancing age, previous cataract surgery, myopia and trauma. Patients generally present with symptoms such as light flashes, floaters, peripheral visual field loss and blurred vision. Retinal detachment is a serious medical emergency that generally requires prompt surgical intervention (6, 7). According to a pharmacoepidemiolo - gical study, current use of oral fluoroquinolones was associated with an increased risk of developing retinal detachment (7).

Ophthalmic fluoroquinolones were excluded from the study to avoid reverse causality bias. The study identified 445 cases of retinal detachment involving oral fluoroquinolone use in a cohort of 989 591 patients from British Columbia who visited an ophthalmologist between January 2000 and December 2007.

Further research is needed to confirm whether there is a potential association between retinal detachment and fluoroquinolones as well as to clarify the mechanism of action.

As of 31 December 2012, Health Canada received one report of retinal detachment suspected of being associated with the use of an oral fluoroquinolone. The report described a 52-year-old woman who experienced retinal detachment after a course of ciprofloxacin prescribed to treat a bladder infection. Limited evidence linking retinal detachment to oral fluoroquinolones may explain the low level of reporting to Health Canada.

References

1. Cipro (ciprofloxacin) [product monograph]. Toronto (ON): Bayer Inc.; 2012.
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5. Ofloxacin (ofloxacin) [product monograph]. Toronto (ON): AA Pharma Inc.; 2010.
6. Gariano RF, Kim CH. Evaluation and management of suspected retinal detachment. *Am Fam Physician* 2004;**69**(7):1691-8. [PubMed]
7. Etminan M, Forooghian F, Brophy JM et al. Oral fluoroquinolones and the risk of retinal detachment. *JAMA* 2012;**307**(13):1414-9.

Health Canada advised withdrawal of Calcitonin nasal spray from market

Health Canada has advised of the market withdrawal of all synthetic calcitonin nasal spray products (Miacalcin ®, Sandoz Calcitonin® and Apo-calcitonin®) with effect 1 October 2013. All three products are authorized in Canada for the treatment of postmenopausal

osteoporosis in females five years post menopause with low bone mass relative to healthy pre-menopausal females. Health Canada has concluded, in light of a newly identified risk of cancer, that the benefit-risk profile for the treatment of postmenopausal osteoporosis is no longer considered favourable. As of 3 July 2013, manufacturers have ceased the sale of synthetic calcitonin nasal spray products.

Reference: *Health Canada Advisory,* 31 July 2013 at http://healthycanadians.gc.ca/ recallalert-rappel-avis/hc-sc/2013/34781a-eng.php

Operation Pangea VI: combating sale of unapproved medicines United States of America

The Food and Drug Administration and international regulatory and law enforcement agencies have taken action against more than 9600 web sites that illegally sell potentially dangerous, unapproved prescription medicines to consumers. This action includes issuance of regulatory warnings and seizure of offending web sites and over 41 million US dollars' worth of illegal medicines worldwide. The action occurred as part of the 6th annual International Internet Week of Action (IIWA), a global cooperative effort to combat the online sale and distribution of potentially counterfeit and illegal medical products. The goal of Pangea VI — which involves law enforcement, customs, and regulatory authorities from 99 countries — was to identify the makers and distributors of illegal drug products and medical devices and remove these products from the supply chain.

As part of this international effort, the FDA Office of Criminal Investigations, incoordination with the United States Attorney's Office for the District of Colorado, seized and shut down 1677 illegal pharmacy web sites. The effort ran from 18–25 June 2013. Many of these web sites appeared to be operating as a part of an organized criminal network that falsely purported to be "Canadian Pharmacies." These web sites displayed fake licences and

certifications to convince U.S. consumers to purchase drugs they advertised as "brand name" and "FDA approved." The drugs collected as part of Operation Pangea were not from Canada, and were neither brand name nor FDA approved. These web sites also used certain major U.S. pharmacy retailer names to trick consumers into believing an affiliation existed.

Reference: *FDA News Release,* 27 June 2013 at http://www.fda.gov/NewsEvents/ Newsroom/PressAnnouncements/ucm358 794.htm

China must improve drug quality to enter European market, says consultant

Chinese pharmaceutical manufacturers will need greater focus on high-quality standards if they wish to enter European markets, said the health care consultant firm Diapharm after meeting with a delegation from the Chinese Chamber of Commerce for Import & Export of Medicines & Health Products. Diapharm, based in Munster, Germany, said it was opening an office in Shanghai to help Chinese firms meet EU Good Manufacturing Standards. OutSourcing-Pharma.com

Indian state begins free distribution of generic medicines

The state of Kerala in India has launched a program of free distribution of generic drugs for diseases including cancer and heart conditions through all government-run hospitals and clinics. Government pharmacies plan to stock more than 900 generic medications, although a shortage of licensed pharmacists has raised concerns. PharmaBiz.com (India)

India approves foreign pharmaceutical investments

India's Foreign Investment Promotion Board has cleared 15 proposals for foreign direct investment amounting to $322.58 million. The approvals covered such firms as Advanced Enzyme Technologies, Symbiotec Pharmalab and Jubilant Pharma. BioSpectrum Asia

U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER) , seek comments on "Guidance for Industry on ANDA Submissions — Refuse-to-Receive Standards "

This guidance document is being distributed for comment purposes only and is available at https://www.federalregister.gov/articles/2013/10/01/2013-23793/draft-guidance-for-industry-on-abbreviated-new-drug-application-submissions-refuse-to-receive

Comments and suggestions regarding this draft document should be submitted within 30 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

Merck to lay off 8,500 workers to reduce costs

The New York Times reports that according to an announcement made on Tuesday, the pharmaceutical company Merck will lay off nearly 8,500 employees, reducing costs by nearly $2.5 billion within the next two years and restructuring its research and development unit, which has fallen victim to major setbacks over the last few years. The company's operations would be consolidated to a facility in Kenilworth, NJ, closing both the Summit and Whitehouse Station locations. Kenneth Frazier, Merck's chief executive, stated that these actions were taken to make the company more competitive and "better positioned to drive innovation." Merck announced that the cost cuts will be completed by the end of 2015 and $1 billion in reductions will be accomplished by the end of 2014.

On its front page, the Wall Street Journal reports that the company will be discontinuing or out-licensing particular medications in late-stage development, putting increased emphasis on the acquisition of experimental pharmaceuticals from outside of the company. Merck believes that doing so will protect the company in the long run, minimizing costly research fizzles.

Bloomberg News reports that Frazier clarified that core therapeutic areas would become the company's main focus, putting more resources towards hospital care, diabetes, cancer and vaccines, while the resources for other therapeutic areas will be reduced significantly. The chief executive officer added that for the company to successfully develop medicines with the greatest sales potential, researchers must work closely with the business side of the company.

Forthcoming Event

DIA India
8th Annual Conference
October 24-26, 2013
NIMHANS Convention Centre, Bangalore, India
For details: www.diahome.org