Quinine sulfate: risk evaluation for hematological reactions

Due to continued reports of serious side effects in patients using Quinine sulfate (Qualaquin®) “off-label” for night-time leg cramps, the Food and Drug Administration (FDA) has approved a risk management plan to warn against the use of this drug for such unapproved uses. Qualaquin® should not be used for night time leg cramps. Its use may result in serious and life-threatening hematological reactions, including serious bleeding due to thrombocytopenia and haemolyticuraemic syndrome/thrombotic thrombocytopenic purpura, which in some cases may result in permanent kidney damage. In some patients, adverse reactions result in hospitalization and death. Qualaquin® is approved for the treatment of uncomplicated malaria caused by the parasite Plasmodium falciparum, primarily in travellers returning from malarial endemic areas.


Methylnaltrexone bromide: gastrointestinal perforation

The manufacturer of methylnaltrexone bromide (Relistor® Subcutaneous Injection) has provided important new safety information. Methylnaltrexone bromide is indicated for the treatment of opioid-induced constipation in patients with advanced illness who are receiving palliative care. When response to laxatives has been insufficient, methylnaltrexone bromide is used as an adjunct therapy to induce a prompt bowel movement. Patients with advanced illness may be at increased risk of gastrointestinal (GI) perforation if they have conditions associated with localized or diffused reduction of structural integrity in the GI wall. The risks and benefits of Relistor® treatment should be weighed for each patient.

What is the deadliest disease in the world?

Q: What is the deadliest disease in the world?

A: The results of ranking the leading causes of death are subject to the cause categories used. The broader the cause categories used, the more likely they will rank among the top leading causes of death.

According to the estimates in The global burden of disease: 2004 update, which was published in 2008, there were 59 million deaths in the world in 2004. The broad category of all "noncommunicable diseases" killed 35 million people; communicable diseases, maternal and perinatal conditions, and nutritional conditions killed 18 million people worldwide; and external causes of injuries killed 6 million people.

The following are the leading causes of death:

<table>
<thead>
<tr>
<th>No.</th>
<th>Cause</th>
<th>Estimated number of deaths (in millions)</th>
<th>Percent of all deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Ischemic heart disease</td>
<td>7.2</td>
<td>12.2</td>
</tr>
<tr>
<td>2</td>
<td>Cerebrovascular disease</td>
<td>5.7</td>
<td>9.7</td>
</tr>
<tr>
<td>3</td>
<td>Lower respiratory infections</td>
<td>4.2</td>
<td>7.1</td>
</tr>
<tr>
<td>4</td>
<td>Chronic obstructive pulmonary disease</td>
<td>3.0</td>
<td>5.1</td>
</tr>
<tr>
<td>5</td>
<td>Diarrhoeal diseases</td>
<td>2.2</td>
<td>3.7</td>
</tr>
<tr>
<td>6</td>
<td>HIV/AIDS</td>
<td>2.0</td>
<td>3.5</td>
</tr>
<tr>
<td>7</td>
<td>Tuberculosis</td>
<td>1.5</td>
<td>2.5</td>
</tr>
<tr>
<td>8</td>
<td>Trachea, bronchus, lung cancers</td>
<td>1.3</td>
<td>2.3</td>
</tr>
<tr>
<td>9</td>
<td>Road traffic accidents</td>
<td>1.3</td>
<td>2.2</td>
</tr>
<tr>
<td>10</td>
<td>Prematurity and low birth weight</td>
<td>1.2</td>
<td>2.0</td>
</tr>
<tr>
<td>11</td>
<td>Neonatal infections(^a)</td>
<td>1.1</td>
<td>1.9</td>
</tr>
<tr>
<td>12</td>
<td>Diabetes mellitus</td>
<td>1.1</td>
<td>1.9</td>
</tr>
</tbody>
</table>

Source: Global Burden of Disease: 2004 update
FDA Approves Once-Daily Schizophrenia Drug.

Reuters reports that the FDA approved the oral schizophrenia drug Latuda (lurasidone HCl), according to a New Jersey subsidiary of Dainippon Sumitomo Pharma Co Ltd. The once-daily drug is expected to be available by the first quarter of 2011 and will compete with Novartis' twice-daily Fanapt [iloperidone].

The agency approved Sunovion's medication Latuda (lurasidone HCl) "based on four studies that showed patients taking the drug had fewer schizophrenia symptoms than patients taking placebo," the AP reports.

The Boston Globe "Business Updates" blog reported that the medication is taken orally once a day. According to Sunovion's press release, the medicine offers "a first-line treatment option for patients with schizophrenia and is expected to be available in the US during the first quarter of 2011."

Notably, Health Day added, the drug "is an atypical antipsychotic drug. All medications in this class contain a boxed label warning that prescribing them for unapproved use in people with dementia-related psychosis increases the risk of death."

Pharma Whistleblower Gets $96 Million Payout

A whistleblower who exposed contamination problems at GlaxoSmithKline's pharmaceutical manufacturing operations has been awarded $96 million. The payment is thought to be the biggest ever handed to a US whistleblower. It was awarded after an eight-year fight, which ended yesterday, when Glaxo agreed to pay the US government $750 million to settle civil and criminal charges that it manufactured and sold adulterated drug products.

Source: Pharmalive.com

Text of letter by Indian Civil Society Groups, to the Indian Prime Minister, regarding takeover of Indian Drug Companies by MNCs.

19/10/2010

Dr. Manmohan Singh
Hon'ble Prime Minister of India
The Prime Minister's Office
South Block, Raisina Hill,
New Delhi, India-110 011.

Subject: Takeover of Indian Pharma Companies by MNCs and the visit of PhRMA delegation to India on 21st October

Dear Dr. Manmohan Singhji,

We the undersigned are writing to you on a matter of vital concern for a large number of people in the country.

India is, today, the 4th largest producer of drugs in the world and a world class supplier of relatively cheap generic medicines. It is the largest supplier in the world of low-priced anti-retrovirals and exports medicines to over 200 countries. The pharma sector is a major foreign exchange earner, only next to the IT sector, with a turnover in excess of Rs. one billion.

However, major concerns regarding access to medicines in the country remain. The World Health Organisation (WHO) has reported that about 68 crore people, i.e., 65% of Indians are without access to essential medicines. Instead of building on the excellent manufacturing capacity to make available essential medicines for all, there has been
progressive undermining of these gains especially in recent years.

All the three major developments which resulted into India becoming the ‘pharmacy of the world’ have now been reversed -- the Indian Patents Act of 1970; initiation of manufacture of medicines from the basic stage by Indian public sector companies in the sixties; and the 1978 Drug Policy that imposed several restrictions on the operations of foreign companies while providing preferential treatment to Indian companies. The 1979 Drug Price Control Order (DPCO), that imposed price control over 347 medicines has also been undermined by reducing the number of medicines under price control to only 76. Many in civil society and health professionals continue to express concerns about galloping medicine prices; increase in wasteful, irrational combinations of medicines; and de-industrialisation in the pharmaceutical sector in India.

Takeover of Indian Pharma Companies: India's Health Security Affected

The immediate cause of concern, and the reason for this letter, is the series of take over of important Indian companies by MNCs and the trend towards domestic companies becoming junior partners of MNCs through tie-ups. Six major acquisitions of Indian companies have taken place in the last 4 years -- Ranbaxy, Dabur Pharma, Shanta Biotech, Piramal Health Care, Matrix Lab and Orchid Chemicals, and more are on the anvil. Further, there have been several other tie-ups between MNCs and domestic companies - viz. GSK with Dr Reddy's; Pfizer with three companies - Aurobindo, Strides Arcolab and Claris Life Sciences; Abbot with Cadilla Health Care and Astra Zeneca with Torrent.

Recently, a paper circulated by the Department of Industrial Policy and Promotion (DIPP) has pointed out that:  “There is a concern that their takeover by multinationals will further orient them away from the Indian market, thus reducing domestic availability of the drugs being produced by them”. The reversal of production trends in the drug market is clear from the fact that of the 10 largest drug companies in India in 1998-99, only one (Glaxo Smith Kline) was a foreign company, while today three of the top ten companies are foreign owned (Ranbaxy, Glaxo Smith Kline and Piramal). The Indian drug industry, built by diligent application of public policy that sought to achieve self reliance in the pharmaceutical sector and availability of medicines at affordable prices, is poised to be handed over to Foreign Multinational corporations. These developments clearly affect India’s health security negatively.

It is in this context that we note with concern reports in the media that a delegation from PhRMA (the representative of US based drug companies) is to visit India from October 21, 2010 to meet with different Ministries of the Government of India. We understand that the delegation is particularly interested in discouraging the Indian Government from applying a cap on FDI in the pharma sector and from issuing compulsory licenses for patented medicines. We are strongly of the opinion that an FDI cap on foreign ownership of pharma companies and liberal use of compulsory licenses are two vital avenues open to India to find ways to ensure much wider access to essential medicines to it’s citizens. We demand that the Indian Government be firm in keeping these options available to us in the future in order to strengthen self- reliance and not succumb to pressure by US based companies and the US Government.

We urge that the Government operationalise the following measures to rescue India from the opprobrium of being home to the largest number of people without access to essential medicines:
* Scrutinise the spate of acquisition of Indian companies by MNCs and explore whether anti-competitive provisions of our Competition law are being violated
* Examine the existence of collusive behavior and abuse of monopoly through intellectual property rights and resultant high prices of patented drugs in India.
* Instead of automatic approval, FDI in the pharma sector be routed through Foreign Investment Promotion Board (FIPB) with an imposition of an FDI cap of 40%
* Liberal use of the compulsory license (CL) provisions of the Indian Patents Act to secure access to patented medicines and therefore lower costs of medicines
* Scrapping of the loan license system and contract manufacturing to discourage big companies from reducing their manufacturing activity
* Formulate appropriate policies to incentivise bulk drug manufacture by Indian companies over import of bulk drugs
* Resist attempts to introduce measures such as data exclusivity, or to dilute/remove Section 3d of the Indian Patents Act, especially through bilateral/multilateral FTAs.
* Revive Public Sector units through a robust plan and infusion of adequate resources, to ensure production of essential medicines and to provide security in emergency situations arising out of calamities such as war, natural disasters and epidemics.

You will appreciate that the concerns we raise are of vital importance to the nation. We seek your personal intervention in the matter.

Thanking You,

Yours Sincerely,

Dr. Amit Sengupta-All India Peoples Science Network, Dr. Mira Shiva - All India Drug Action Network/Initiative for Health and Equity in Society, Dr. Gopal Dabade - All India Drug Action Network/Drug Action Forum - Karnataka, Loon Gangte - Delhi Network of Positive People (DNP+)/ITPC, Amitava Guha - Federation of Medical Representatives Assns. of India (FMRAI), Dr. B. Ekbal - Jan Swasthya Abhiyan, Prabir Purkayastha - Knowledge Commons, S. Srinivasan - LOCOST, K. M. Gopakumar - Third World Network, Dr. Anant Phadke - Medico Friends Circle, Dr. C. M. Gulhati - Editor, MIMS, Dr. Narendra Gupta - Prayas, Rajasthan, N. B. Sarojini - Sama – Resource Group for Women & Health Source: ip health

Forthcoming Events:

Reader’s Column:

Prof. A.B.M. Faroque  Sat, Oct 23, 2010 at 11:02 PM
<abmfaroque@yahoo.com>
To: IPA Bengal Branch Drug Information Centre <ipabengal.dic@gmail.com>

Many thanks for sending me your valuable bulletin.

Regards.

Prof. A B M Faroque
University of Dhaka

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