Drug Information Bulletin

Drug Information Centre (DIC)

Indian Pharmaceutical Association

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Regulatory Affairs Division (RAD), IPA

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Content

Editorial

The year 2015 has started remarkably with several developments in the health care system of India. The Department of Health and Family Welfare proposes to introduce the Drug and Cosmetics (Amendment) Bill, 2015 in the Budget Session of the Parliament. The said is placed in public domain (http://www.mohfw.nic.in/) with a view to elicit the comments/views of the stakeholders including the general public. The comments/views may be forwarded to Dr. Shailendra Kumar, Director (Drugs), Department of Health and Family Welfare, Room No-301 'D' Wing, 3rd Floor, Nirman Bhawan, New Delhi-110011 or emailed at anita.tripathi76@nic.in latest by ***January 12, 2015. As a result of requests from several stakeholders the last date has been extended up to 19th January 2015.***

Government of India has appointed a committee for giving recommendation for amendment of Drugs and Cosmetics Rules 1945 to make it contemporary. It has also invited suggestions from association concerned with Drugs, Cosmetics and Medical Devices industry and trade vide a notification dated 24th December 2014. Suggestion / inputs should reach at anita.tripathi76@nic.in latest by ***January 15, 2015.***

Another development is that a draft National Health Policy 2015 has also been published and hosted at http://www.mohfw.nic.in/ for comments, which should be provided online before ***28th February 2015****. This is a golden opportunity for the pharmacists to give inputs for proper utilization of the large pool of pharmacists in the national health care system. Hope all Pharmaceutical organizations will take this opportunity providing their suggestions / inputs in all three matters.*

Dr. Subhash C. Mandal
Editor

New Drug: Pasireotide Diaspartate

Approved indication: Cushing's disease
Signifor
Ampoules containing 900 microgram/mL

Cushing's disease is caused by pituitary adenomas which secrete adrenocorticotrophic hormone (ACTH). Surgical treatment helps most patients, but some do not enter remission and others relapse. Pasireotide is an option for these patients and is also indicated for those who cannot have surgery.

The pituitary adenomas contain receptors for somatostatin (growth hormone release inhibiting factor). Pasireotide is an analogue of somatostatin which binds to these receptors. This inhibits the secretion of ACTH.

To test the hypothesis that pasireotide would work in Cushing's disease the drug was injected twice a day by patients who had 24-hour urinary free cortisol at least twice the upper limit of normal. After 15 days, 22 of 29 patients had reduced cortisol. In 5 of them, the urinary cortisol returned to normal. Average concentrations of plasma ACTH and serum cortisol also reduced.1

A phase III trial studied 162 patients with Cushing's disease who had levels of 24-hour urinary free cortisol at least 1.5 times the upper limit of normal. They were randomised to receive twice-daily injections of pasireotide 600 microgram or 900 microgram. If the urinary cortisol level was more than twice the upper limit of normal after three months, the dose was increased by 300 microgram twice daily for a further three months. The primary end point of the double-blind trial was at six months, but the trial continued with an open-label phase for a further six months. The mean duration of treatment was 10.8 months.2,3

Urinary free cortisol declined rapidly. By six months 15% of the patients given 600 microgram and 26% of those given 900 microgram had levels within the normal range. After 12 months the corresponding figures were 13% and 25%. Clinical changes at 12 months included an average weight loss of 6.7 kg and decreased mean blood pressure (–6.1 mmHg systolic, –3.7 mmHg diastolic). There were also improvements in triglycerides and low density lipoprotein cholesterol.2

Glucose intolerance is common in Cushing's disease, but this did not improve with treatment. By the end of the study 51 of the 107 patients who did not have diabetes at the start of the study had become diabetic (glycated hemoglobin of more than 48 mmol/mol or 6.5%). A new hypoglycaemic drug had to be started in 74 of the 162 patients in the phase III trial.2

Pasireotide is given by subcutaneous injection preferably into the abdomen or top of the thigh. Approximately 17% of patients will have injection-site reactions. Although pasireotide is not metabolised it is eliminated in the bile so liver disease will increase exposure to the drug. Approximately 30% of patients develop cholelithiasis,2 so ultrasound scans of the gall bladder are recommended before and during treatment. Liver enzymes can increase so liver function tests are recommended before treatment, after one or two weeks and then monthly for the first three months of treatment. Sustained changes in liver function are an indication for stopping pasireotide permanently. Severe liver disease is a contraindication.

The most frequent adverse effects of pasireotide are nausea and diarrhoea. Abdominal pain and headache are also common. In some patients the reduction in cortisol in response to pasireotide caused symptoms of hypocortisolism. Hypopituitarism can also occur. The drug can prolong the QT interval on the ECG and cause bradycardia. There is therefore a risk of interaction with drugs such as beta blockers and antiarrhythmic drugs. There have been no clinical studies of drug interactions. There were also no studies in children, pregnant or lactating women.

Only a minority of patients have a complete response to pasireotide. In the phase III trial only 48% of the patients continued the drug for 12 months.2 The main cause of discontinuation was lack of efficacy. Increasing the dose may not increase efficacy. The drug should probably be stopped if there has been no response after two months of treatment. The combination and comparison of pasireotide with other treatments requires further research.

References:

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2. Colao A, Petersenn S, Newell-Price J, Findling JW, Gu F, Maldonado M, et al. A 12-month phase 3 study of pasireotide in Cushing's disease. N Engl J Med 2012;366:914-24.
3. Pivonello R, Petersenn S, Newell-Price J, Findling JW, Gu F, Maldonado M, et al. Pasireotide treatment significantly improves clinical signs and symptoms in patients with Cushing's disease: results from a Phase III study. Clin Endocrinol (Oxf). 2014 Feb 17. doi: 10.1111/cen.12431. [Epub ahead of print]

Source: Aust Prescr 2014; 37:100-7

New antibiotic shows promise in treating drug-resistant bacteria

An antibiotic isolated from New England dirt has successfully treated mice infected with drug-resistant staphylococci bacteria, according to a study in Nature. Teixobactin has yet to be tested in humans. "It should be used, if it gets successfully developed, as broadly as possible, because it is exceptionally well-protected from resistance development," said NovoBiotic Pharmaceuticals co-founder Kim Lewis, a study author.

For details: www.nature.com/articles/nature14193

India asks FDA to include local officials during drug facility inspections

The Indian government has asked the FDA to allow its local officials to join its inspections of domestic pharmaceutical facilities due to the rising number of Indian drugmakers facing regulatory action by the FDA for alleged irregularities at their sites. "Cultural differences and body language may (sometimes) widen the gap (during FDA inspection)," said PV Appaji, director general of India's Pharmaceuticals Export Promotion Council, adding that the FDA used to give companies advance notice of inspections. FDA Commissioner Margaret Hamburg has said inspection practices in India are the same as in the U.S.

Source: Business Standard (India)/Press Trust of India

China to allow online sales of prescription drugs as early as this month - sources

SHANGHAI, Jan 9 (Reuters) - China will allow online sales of prescription drugs as early as this month, a policy that will open up an over 1 trillion yuan ($161 billion) market to online pharmacy operators like Alibaba Group Holding Ltd and Wal-Mart Stores Inc.

The China Food and Drug Administration (CFDA) is finalising which prescription medicines to approve for sale, a senior healthcare policy adviser told Reuters.

The policy would help reform a fragmented and opaque market controlled by state-run distributors and hospitals, brought into the spotlight last year by a bribery case which saw drugmaker GlaxoSmithKline PLC fined nearly $500 million.

"The policy will be released in January or February and the CFDA is actively working on it," said the adviser, who was not authorised to speak with media on the matter and so declined to be identified.

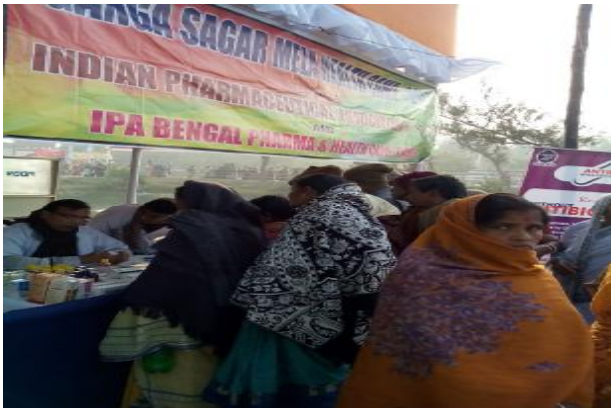
Hospitals currently account for around 70 percent of drugs sold to consumers. Among retailers, online pharmacies are restricted to selling over-the-counter medicines and healthcare products such as cough remedies and vitamin tablets.

The new policy could eventually allow online retail pharmacies such as Alibaba Health Information Technology Ltd and the pharmacy platform of JD.com Inc to wrest sales from hospitals.

Frank Zhao, chief financial officer at pharmacy chain China Jo-Jo Drugstores Inc, said the CFDA had was reviewing the list of prescription drugs for sale online.

"It may be a couple of days or weeks before the final list," he said.

Pics from Gangasagar Health Camp organized by IPA Bengal Branch jointly with IPA Bengal Pharma & Health Care Trust during 10th -16th Jan 2015



Forthcoming Event:

66th Indian Pharmaceutical Congress

23rd – 25th January 2015

Hitex, Hyderabad

Organizer:

Indian Pharmaceutical Congress Association

Host:

All India Drugs Control Officers' Confederation

Exhibition:

FICCI

For details: www.66ipchyd.com