DIC News Letter

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News Journal of
DRUG INFORMATION CENTRE, KSPC

Message from President

I am pleased to present this first issue of Drug Information Center Bulletin published by the Council, which is another feather in the cap. After successfully establishing the Drug Information Center, we thought it is the right time to come out with a bulletin of our own. This will be a bridge between the council and the constituents.

Karnataka State Pharmacy Council is a Statutory body constituted by the Government of Karnataka under the provisions of the Pharmacy Act of 1948. The main function of the *Karnataka State Pharmacy Council* is to grant Registration to the eligible pharmacists possessing requisite qualification as enunciated in the Pharmacy Act and to enforce the provisions of the Pharmacy Act. The ***Karnataka State Pharmacy Council*** is the first council to have all the technical data computerized and issue identity cards to all practicing Pharmacists. The council has also launched Community Pharmacy Programs & Continuing Education Programs to update pharmacists' knowledge. **Most important of all, this is the first council** to set up the Drug Information Centre, which is the first of its kind in the entire country.

In addition to the main function of Registration, the Council has expanded it's activities into the following areas:

❖ PHARMACIST SOCIAL SECURITY SCHEME :

The members of *Karnataka State Pharmacy Council* have constituted *Karnataka Pharmacy Council Registered Pharmacist Welfare Trust* (KPCRPWT) to provide financial security to the survivors of the Registered Pharmacist in the State of Karnataka. This is the first scheme of its kind in this country designed **for the pharmacists by the pharmacists themselves.**

❖ CONTINUING EDUCATION :

CONTINUING EDUCATION for the Registered Pharmacists has been started by *Karnataka State Pharmacy Council* in 1998-99. The first programme was conducted in Bangalore and the second was at Hubli. This will be an ongoing process scheduled to be held all over the State.

❖ APPOINTMENT OF PHARMACY INSPECTORS:

Karnataka State Pharmacy Council has appointed Pharmacy Inspectors under section 26(A) of the Pharmacy Act, 1948. The Pharmacy Inspectors are instructed to inspect premises where dispensing is carried out.

❖ DRUG INFORMATION CENTRE :

Recognizing the growing need of up-to-date drug information by the healthcare professionals, the council has started the Drug Information Centre, which can proudly say it is the first major venture in the country.

Drug Information Centre - Primary Objectives

- To provide in-depth and unbiased source of crucial **drug information in the Indian context** to meet the needs of the practicing physicians, pharmacists and other health care professionals.
- To promote safe, effective, rational and economic use of drugs in patients by provision of drug information.
- To disseminate the latest advances in patient care through Newsletter.

Our principle resources include

Drug database from **Micromedex includes Drugdex, Martindale, Physicians Desk Reference** etc., Drug database from **Drug Facts and Comparison;** A current collection of texts and files on various drug related information; Internet access for e-mail, web searching and access to external databases; and several online subscriptions.

A website has been hosted by the Council to facilitate the accessibility of the healthcare professionals & the public to utilise the resources of the Center.

Keep us posted of your comments and suggestion so that the bulletin will improve as the days go by.

Wishing you all the best, I remain,

QUOTE

New scientific truth does not triumph by convincing its opponents and making them see the light, but rather because its opponents eventually die and a new generation grows up that are familiar with it.

Max Planck.

UPDATE ON KSPC

GUEST LECTURES

The *Karnataka State Pharmacy Council* recently organized a guest lecture on "Drug Information –A Global Perspective" by **Mr. Graeme Vernon**, a senior Drug Information Practitioner, Austin & Repatriation Medical Centre, Australia.

More than 40 participants representing academicians, hospital pharmacists, regulatory authorities and pharmacy administrators attended the lecture. In this lecture Mr. Vernon discussed the importance of establishing Drug Information Center and methods of training a pharmacist to become a drug information practitioner. The sources of information such as primary, secondary and tertiary sources had been dealt in detail. The book such as Australian Therapeutic Guidelines and Therapeutic Guidelines for different category of drugs was shown through slides. He recommended that Drug Information Centers should have these ready reference books. Also, he mentioned about the importance of internet, E-mailing system etc, which are useful to understand the functioning of Drug Information Centers. On the whole, the lecture was useful to pharmacists interested in pursuing their career in Drug Information Practice.

Concluding the session, Mr. Graeme Vernon highly appreciated the initiative taken by the *Karnataka State Pharmacy Council* in establishing a Drug Information Center to provide authentic source of drug information to all.

The *Karnataka State Pharmacy Council* recently organised a guest lecture on "New Drug Development : A regulatory overview" by **Dr. G. Jagadeesh**, a pharmacologist at US FDA and an adjunct scientist at National Institutes of Health, USA. More than 30 participants from leading pharmaceutical industries of Bangalore attended the lecture.

Delivering the lecture, Dr. Jagadeesh traced through the various steps of the process of discovering a drug. The steps from test tube to new drug application review were explained in depth. Technical expertise in the early process of drug discovery, stages in new drug development, timing and duration of studies necessary to support clinical trials and preclinical studies was dealt in detail. The lecture on the series of developmental and evaluative steps considered before drugs can be marketed successfully, was well received by the participants.

CONTINUING EDUCATION PROGRAMME

The *KSPC* has been seriously involved in the process of bringing about change in pharmacy practice and education. The Council believes that the time has come to demonstrate to the patients and fellow health care providers that pharmaceutical care is one of the health care' s important values. In view of this, *KSPC* had jointly organised a two day Continuing Education program and update in Tuberculosis for practicing pharmacists at Hubli, along with Pharmacy Council of India, New Delhi; Indian Pharmaceutical Association, Karnataka State Branch and K. L. E. S College of Pharmacy, Hubli.

The Chief Guest was **Dr. C. K. Kokate, President,** PCI & Chairman, Southern Regional Committee, AICTE. The program was presided by Shri. Prabhakar B. Kore, Chairman, Board of Management, K. L. E. Society, Belgaum. Shri R. Anand Rajashekar, Drugs Controller, Government of Karnataka and President IPA, Karnataka Branch was the Guest of Honour.

On the first day, topics, like Drug-Drug and Drug-Food Interactions, Pharmacist's Role in Patients Compliance and others were dealt with. The next day was devoted totally to the Menace of Tuberculosis, wherein Diagnosis and Management of TB was dealt by eminent doctors. The pharmacists were also educated on Patient Counseling on Anti-Tubercular Drugs.

This two day program at Hubli for 40 practicing pharmacists was well appreciated by all. The program was well received by the pharmacists and their suggestions for future program, feedback and evaluation was also taken care by *KSPC*.

ADVERSE DRUG REACTIONS

Over two decades ago, an editorial on drug interactions in the Lancet (19 April 1975) said that "publication of huge lists and tables will induce in doctors a **drug interaction-anxiety syndrome** and lead to therapeutic paralysis".

Knowledge of the 'state of the art' has much advanced since the 1980s and what were then novel and scientifically interesting interactions are now established and well recorded interactions in the standard books of reference.

Perhaps one of the most troublesome and well reported of food-drug interactions was the interaction between tyramine containing foods and MAOI-antidepressants during the early 1960s. Deaths from eating cheese while taking MAOIs was given great publicity and this type of interaction did much to create an awareness of the potential of foods to interact with medicines.

Within two decades,monitoring of adverse drug reactions has developed very rapidly.

FOR YOUR INFORMATION

REPORTS OF ADVERSE EVENTS WITH FLUOROQUINOLONES

The United States Food & Drug Administration, is asking prescribers and pharmacists to alert patients and other caregivers to the potential for tendinitis and tendon rupture while taking or after taking antimicrobial fluoroquinolones. The agency has taken steps to have the package insert revised for the following antimicrobial agents: Ciprofloxacin, Enoxacin, Lomefloxacin, Norfloxacin, and Ofloxacin.

Letters have been issued to the manufacturers requesting that they revise their package inserts to include the following information:

The WARNINGS section will have a new paragraph that should read: "Ruptures of the shoulder, hand, and Achilles tendons that required surgical repair or resulted in prolonged disability have been reported with [the specific drug name]. [The specific drug name] should be discontinued if the patient experiences pain, inflammation, or rupture of a tendon. Patients should rest and refrain from exercise until the diagnosis of tendinitis or tendon rupture has been confidently excluded. Tendon rupture can occur at any time during or after therapy with [the specific drug name]."

As an added precaution, the following statement will be added to the Information for Patients subsection of the PRECAUTIONS section: "Patients should be advised to discontinue treatment and inform their physician if they experience pain, inflammation, or rupture of a tendon, and to rest and refrain from exercise."

(FDA Medical Bulletin * October 1996 * Volume 26 Number 3)

This column will carry more of such information in the subsequent issues.

FACTS ABOUT ANALGIN®

Dipyrone is an analgesic with anti-inflammatory and antipyretic properties. It is the sodium sulphonate derivative of Amidopyrine or Aminopyrine and like phenylbutazone, it is a member of the pyrazolone group of chemicals. **The drug was first introduced by the German manufacturer, Hoechst, in 1922.** Dipyrone is known by many names: **Analgin®, Metamizol®**, etc.

The US Food and Drug Administration, which in 1977 withdrew approval of dipyrone because of its association with **agranulocytosis** and because of the availability of "alternative drug products".

Between July 1981 and July 1986, 94 people in Germany, where Hoechst is based, did die after taking products containing dipyrone. **Agranulocytosis (severe loss of white blood cells, due to bone marrow damage) was the reason for 46 of the deaths, while 39 were due to anaphylactic shock, a severe allergic reaction.**

Due to these deaths, in 1987 the German drug regulatory authority placed all dipyrone products on prescription & restricted their indications to severe pain after surgery or trauma, colic or tumour pain. All combination drugs containing dipyrone were **withdrawn** except for combination products containing a spasmolytic (like Baralgan®/ Baralgin®), which were temporarily suspended pending resolution of an injuction taken out by another manufacturer. Hoechst **"voluntarily" withdrew Baralgan® from the German market at the beginning of 1987.**

However, Dipyrone continues to be a **popular** and **profitable pain killer in many countries.** In 1987, Hoechst's two dipyrone products-Novalgin® and Baralgan®- brought in more than US $ 190 million, just over 5% of its total world drug sales. In 1991, Novalgin® alone contributed 2.3% of the company's total sales and was Hoechst's sixth most popular drug with global sales of some $125 million.

In most parts of the world, products containing dipyrone are being promoted not as drugs of last resort, but for everything from headaches to dysmenorrhea.

Dipyrone has been banned or severely restricted in Australia, Bangladesh, Canada, Denmark, Egypt, Fiji, Germany, Greece, Ireland, Isreal, Italy, Japan, Malaysia, New Zealand, Norway, Philippines, Saudi Arabia, Singapore, Sweden, the UK, the USA, and Venezuela, and combination products containing dipyrone have been banned in Pakistan.

In 1990, Baralgan® was India's sixth most sold branded drug on the public market (excluding sales to hospitals or government health centres), with sales reaching $5.2 million.

The continued popularity of dipyrone and other pyrazolones is hard to justify in the face of the evidence of the **risk of agranulocytosis and anaphylactic shock.**

The major markets for dipyrone products now lie in the **developing countries** due to restrictions on sales or outright bans in the industrialised countries

Dipryone is marketed in India under the following brand names:

Analgin® as tablets, Baralgan-M® as tablets & Novalgin® (Hoechst Marion Roussel) as tablets & injection.

(Ref: PROBLEM DRUGS, HEALTH ACTION INTERNATIONAL, 1993)

DRUG REVIEW

NIMESULIDE

It is an old drug with a Belgian patent dating back to 1974 .It has become somewhat of a hand-me-down drug, successively marketed by Boehringer Ingelheim, and it is now mainly manufactured in India by a number of firms.

There has been some revival of interest in the drug because it was claimed, like Meloxicam, to be a **preferential COX-2 inhibitor,** but, like Meloxicam, proof is thin.

Prostaglandins are synthesized from arachidonic acid by the enzyme cyclooxygenase. There are two isoforms of cyclooxygenases: Cox-1 is expressed constitutively in most tissues and helps maintain gastric mucosal integrity; Cox-2 is inducible and is associated with cellular growth and differentiation. Super aspirins that selectively inhibit Cox-2 are being developed by several drug companies to try and avoid the side effects of NSAIDs. Most currently commercially available NSAIDs are nonselective Cox inhibitors and are associated with peptic ulceration in the stomach.

Nimesulide is NOT mentioned in the last edition of the Physician's Drug Reference nor in the British National Formulary. It seems to be **potentially hepatotoxic**, and that is probably the main reason why registration is being held up in the developed countries.

RESPONSE IN OTHER COUNTRIES

In **Italy,** Nimesulide is authorized to be used in **children above 6 years of age** as an antipyretic and as a painkiller.

There were six applications to the **Sri Lankan Drug Regulatory Authority** (DRA) by various manufacturers in 1998. However, **Nimesulide was not registered in Canada, USA, UK, Scandinavia, Australia, and New Zealand**. The Sri Lankan DRA considers these countries to be the reference DRAs and tends to consider only those drugs (the chemical entity, not the product) that are registered by these authorities. Nimesulide is now **unlikely to be registered** in Sri Lanka because of the reports like fulminant hepatic failure with Nimesulide.

The paediatric nimesulide preparation **has now been withdrawn from sale in Portugal and Israel.**

Accion Internacional Para la Salud, an institution in **Peru,** complained to the national drug regulator about the approval of the use of Nimesulide in children as they know that indication in children is not justified or recommended.

The drug regulatory authority in **Nepal** has granted a temporary registration of tablet and paediatric suspension of Nimesulide. The regulatory authority has decided to go cautiously taking advantages of experiences of the countries of the other regions. Should drug regulatory authorities come across any serious complication, the registration is subject to withdrawal quickly. In some children, a prolonged hypothermic effect has been noted. The regulatory has advised concerned physicians that they should take care in adjusting the dose not only on the basis of body weight but also taking into account the age of child under treatment. While considering the alternatives, Aspirin is not suitable for children and Analgin® in all forms including injectable forms is banned. Having found Nimesulide as a relatively safer and effective alternative over existing NSAIDs, the drug was registered for paediatric population as well. A lot of Indian companies are marketing Nimesulide in tablet, ointment, kid dispersible tablets, and paediatric suspension form. Question that has arisen in E-drug-"What should a developing country with little or no information exchange, and inadequate regulation of drugs do, when the harmonised dossiers of the new drugs are submitted for registration? An important issue in registering new drugs in developing countries is whether health or trade should come first. Registering new drugs without delay would help trade and free circulation of goods; but adopting a cautious attitude would serve health. Should not the government ensure that citizens are healthy before they begin to trade?"

(Source: E-Drug)

Additional Information on any article is available on request
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