Drug Information Bulletin

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Content

- **Editorial**
- **Government is procrastinating on setting drug prices: Indian Supreme Court**
- **Greater transparency in drug pricing urged for Ireland**
- **Doctors in India defy guidelines on generic drugs**
- **The long-awaited "Guideline for Elemental Impurities - Q3D" was published**
- **Forthcoming Event**

Editorial

International communities decided to work for overall development of the society under the leadership of UN in 2000 and setup 8 goals to achieve by 2015. The midterm assessment reveals that there is significant development in some sectors, but there are some areas like MDG 4 & 5 where progress is not satisfactory and it is very unlikely to achieve the goal by 2015. Role of the HCPAs including pharmaceutical Associations were emphasized to achieve the MDG 4 and MDG 5. Country groups were formed involving associations of health care professionals including Pharmaceutical Associations. The role of pharmacists was recognized and efforts to involve them in a more extensive manner are in progress. Very unfortunately the flagship project of Govt. of India- NRHM is not utilizing the potential of the pharmacists, though Pharmacists Population ratio in India is better than most of the countries in rest of the World.

Government is procrastinating on setting drug prices: Indian Supreme Court

India's Supreme Court said the government was procrastinating in setting ceilings on the prices of essential drugs, asking it to file its answer to a petition by All India Drug Action Network accusing drug makers of taking excessive profits.

Little has been done by the government in a decade in which drug makers' margins soared from 10% to 1,300% in certain cases, Justice G. S. Singhvi said. The petition seeks to repeal the 2012 National Pharmaceutical Pricing Policy.

Reference: Business Standard (India)

Greater transparency in drug pricing urged for Ireland

Meetings about how to increase competition and reduce prescription drug prices in Ireland's pharmacy sector took place last month between the National Consumer Agency, the Competition Authority and the Troika – which is made up of the European Central Bank, the European Commission and the International Monetary Fund. The National Consumer Agency has decried what it says is a lack of clarity in drug pricing following a survey that found considerable variation in the prices of prescription medicines. The Irish Pharmacy Union pointed out that posting prices for more than 7,000 prescriptions would be "impractical," and that prices are set by the government's Health Service Executive and the major drug manufacturers.

Reference: Independent.ie (Ireland)

Doctors in India defy guidelines on generic drugs

Doctors across India seem unwilling to write prescriptions containing only the generic or unbranded chemical names of drugs, despite two recent advisories from the Medical Council of India urging them to do so.

The advisories, issued in November 2012 and January 2013 asking physicians to 'as far as possible prescribe generic drugs,' are unlikely to change prescription practices in the country, private and government doctors have said.

Some doctors have described the advisories as a fresh reminder of a code of ethics that doctors are expected to follow. In 2002, the Medical Council of India told doctors to prescribe generically to protect patients from the effect of promotional campaigns by drug companies. But many doctors say that the suggestion to prescribe drugs without brand
names is impractical given the diversity of chemical formulations and the stark differences in the prices of drugs from different manufacturers in India.

Generic drugs sold under different brand names dominate the Indian pharmaceuticals market. A McKinsey report had predicted three years ago that patented products will probably make up less than 5% of the projected $55bn pharmaceutical market in India by 2020.

Krishan Kumar Aggarwal, a senior cardiologist in New Delhi who is also head of the ethics committee of the Delhi Medical Council, a state body, told the BMJ: 'Doctors in India are already prescribing generic drugs, but through their brand names. If the authorities want us to prescribe drugs through chemical names, why do they allow so many brand names and why are there such wide price variations?'

Figures from the Monthly Index of Medical Specialities (MIMS), India, suggest that 10 tablets of unbranded cetirizine were available in 2012 for about 1.50 rupees (0.017; Euro0.019; $0.025), while a branded generic product was sold at 27 rupees, and a branded version cost 39 rupees.

'We don't see such price variations in the United Kingdom,' said Chandra Gulhati, editor of MIMS India. For example, Panadol, a branded version of 1000 mg paracetamol, costs 3.30 for 100 tablets, he said, while unbranded 500 mg paracetamol costs 2.88.

Doctors say that the differences in prices of the same drugs and the promotional

campaigns by medical representatives of pharmaceutical companies have given rise to perceptions about the quality of specific brands.

'Perceptions of quality of drugs are not unfounded and cannot just be wished away,' said Vinay Kapoor, a professor and gastrointestinal surgeon at the Sanjay Gandhi Postgraduate Institute of Medical Sciences, in Lucknow.

Earlier this year, India's health ministry told the Indian parliament that of 48,082 samples of drugs tested in 2011 by government drug regulators, 2186 (4.5%) had been found to be of substandard quality. In each of the three preceding years, the proportion of substandard drugs among samples tested ranged from 5.7% to 4.9%.

'The first step should be to ensure quality standards, quality monitoring, and quality assurance' unless doctors become convinced [that] there is uniform quality, independent of the source of the compound, I don't expect doctors in India will routinely write out prescriptions with chemical names of drugs,' Kapoor told the BMJ.

Doctors also point out that writing prescriptions with unbranded generic names would be tantamount to handing over the choice of drug to chemists in retail pharmacies, who are likely to hand over the products that provide them the highest margins.

'We're not comfortable with leaving the choice of the drug to chemists,' said Harivallabh Pai, a paediatrician in Vasco, a town in the western coastal state of Goa, and president of the state branch of the Indian Medical Association.

But not everyone is opposed to the idea. Amar Jesani, a physician and editor of the Indian Journal of Medical Ethics, said that the quality argument was a 'hoax' at times onveniently used to prescribe specific brands.

'Doctors in India rarely think about price considerations,' Jesani told the BMJ. 'With generic prescriptions, at least consumers can demand cheaper drugs - let consumers decide and fight it out with chemists.'

'This debate on generics and unbranded medicines is taking the focus away from the real issue: price control,' said Gulhati. 'The cost of producing 10 tablets of paracetamol remains the same for branded or unbranded products: profit margins vary - not cost of production.'

A government initiative to expand the distribution of generic drugs free through primary health centres and other government healthcare centres is likely to turn state governments into the biggest bulk buyers of unbranded generic drugs.

Health ministry officials point out that the government has earmarked 120bn rupees for this initiative to cover the period between 2012 and 2017. Government procurement agencies will be expected to buy generic drugs in bulk and distribute them to healthcare centres.

'Some states are already doing this, and we're now waiting for feedback from other states to understand requirements,' a senior health official told the BMJ. But public health experts estimate that drugs distributed in government clinics make up less than 20% of drugs consumed in India.

(The article was copied for fair use, which was reported by Ganapati Mudur in BMJ 2013; 347)

The long-awaited "Guideline for Elemental Impurities - Q3D" was published

The long-awaited "Guideline for Elemental Impurities - Q3D" was published on ICH's website on 5 August 2013. According to the different steps of the ICH process it appeared as a Draft Consensus Guideline and is open for comments (deadline not yet specified).

The document contains 9 chapters and 4 Appendices and outlines the principles of,

- Safety assessment (methods used for establishing the PDE for various routes of administration)
- Element classification (assigning the elemental impurities to the classes 1, 2A, 2B, 3 and 4)
- Assessment and control of elemental impurities (taking into accout potential sources of elemental impurites and special considerations for biotechnologically derived products). The principles of quality risk management, described in ICH Q9, should be considered.
- Speciation (separation of elemental impurities based on oxidation state, complexation state or organic combination)
- Analytical procedures
- Life-cycle management of the control strategy for elemental impurities, and
- Recommendations for submission of elemental impurities control strategy

In the Annexes details are given for

- Establishing exposure limits
- Established PDEs for 24 elemental impurities
- Individual saftey assessments of 20 elemental impurities, and
- Illustrative calculation examples for converting PDEs to concentrations.

The guideline applies to new finished drug products and new drug products containing existing drug substances. Drug products containing proteins, polypeptides (recombinant or non-recombinant), their derivatives or conjugates are also covered by this guideline.

Forthcoming Event

Workshop
On

"Botanical Identification & Evaluation of Indian Medicinal Plants" is being organized by the School of Natural Product Studies

November 20 -26, 2013

Organized by:
School of Natural Product Studies
Jadavpur University, Kolkata-700032

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