Drug Information Bulletin

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Content

Editorial

Use of generic medicines is gradually getting popularity. Several countries have already passed suitable legislation to reduce Govt. health expenditure and the cost to individuals of their medicines. Recently Ireland Govt. has passed legislation for introduction of reference pricing and pro-generic initiative.

It may be noted that several state Governments and the Govt. of India has directed the doctors working under the Government health care system to prescribe in generic name. The Medical Council of India has also directed all prescriber to prescribe in generic name as far as possible. These developments will give a fillip in promotion of the concept of Rational Use of Medicines (RUM) and will help to improve access to essential medicines.

Ireland passes reference pricing, pro-generics law

Legislation to enable the introduction of reference pricing and pro-generic initiatives has now been passed by both houses of Ireland's parliament (Oireachtas) and is expected to take effect next month.

Welcoming the passage of the Health (Pricing and Supply of Medical Goods) Bill 2012, Health Minister Dr James Reilly said the legislation gives effect to the government's commitment that reference pricing and greater use of generics will be introduced "to reduce the state's large drug bill and the cost to individuals of their medicines. It will promote price competition and deliver lower medicine prices for both the state and patients," he said.

Currently in Ireland, if a specific brand of medicine is prescribed for a patient, the pharmacist must supply that brand - they cannot supply cheaper generic versions. However, under the Bill, they will now be permitted to substitute medicines which have been designated by the Irish Medicines Board (IMB) as interchangeable.

"It is only where the IMB is satisfied that a medicinal product satisfies all the conditions set out in the Bill that it can do so," noted Alex White, the Minister of State with responsibility for primary care at the Department of Health.

"To further enhance patient safety, the bill allows a prescriber to indicate on a prescription that a branded interchangeable medicinal product should, for clinical reasons, not be substituted," he added.

The Bill also introduces a reference pricing system which will establish the prices that the Health Service Executive (HSE) will pay for products supplied to patients under the General Medical Services (GMS) and community drug schemes. If patients wish to receive a brand that costs more than the reference price, they will have to pay the additional cost out-of-pocket, but in cases where substitution is prohibited for clinical reasons, patients will not pay any additional costs if the prescribed product costs more than the reference price.

Currently, usage of generics in Ireland is very low - patients in the UK are four times more likely to use them - and a third of medical cardholders in Ireland, who now account for more than half the population, are not using generics. However, Teva Pharmaceuticals Ireland has this month launched a campaign to help raise awareness of generic medicines and provide assurances on their safety, quality and affordability.

The campaign, Understandgenerics.ie, is supported by 400 pharmacies nation-wide and fronted by veteran television presenter Gay Byrne. It includes a video at http://bit.ly/hlgenerics.

"Through Understandgenerics.ie, I learned that generics are approved in exactly the same way as all other medicines, guaranteeing that generics meet the required safety and quality standards," says Mr Byrne. "With generics, the name, packet or colour of your medication may change, but what's inside is essentially the same, only more affordable."

However, a group representing people with epilepsy has been campaigning strongly to have anti-epilepsy drugs (AEDs) excluded from substitution, and has expressed strong concern that this exemption was not included in the final Bill.

The risks associated with switching from branded AEDs to generic AEDS, or more particularly from one generic version to another, have been highlighted "on numerous occasions," says the group, Epilepsy Ireland.

"It has been extremely frustrating to see a series of amendments voted down which would have offered safety and reassurance to people with epilepsy. A golden opportunity to enshrine the rights of people with epilepsy has been missed," says the group's chief executive, Mike Glynn.

The challenge now for Epilepsy Ireland is to ensure that the IMB does not designate AEDs as interchangeable, he said. The group will also launch an education campaign to educate people with epilepsy about staying safe, to inform prescribers of the need to write "do not substitute' on AED prescriptions and to ensure that pharmacists do not switch AEDs, said Mr Glynn.

However, he added, Epilepsy Ireland has received reports that AED switching has been taking place even before the Bill was passed.

- The new legislation also sets out statutory procedures governing the supply, reimbursement and pricing of medicines and other items to patients under the GMS and community drugs

schemes. It will allow the HSE to attach conditions to the supply of certain items, provided that any restrictions are evidence-based and in the interests of patients and ensuring value for money, the government adds.

USP–NF Compendial updates

Recently the US-NF updated the following monographs:
Seven New Revision Bulletins:

* Anagrelide Hydrochloride (posted 31-May-2013; official 01-Jun-2013)
* Atorvastatin Calcium (posted 31-May-2013; official 01-Jun-2013)
* Cefdinir for Oral Suspension (posted 31-May-2013; official 01-Jun-2013)
* Griseofulvin Tablets (posted 31-May-2013; official 01-Jun-2013)
* Saw Palmetto Extract (posted 31-May-2013; official 01-Jun-2013)
* Temozolomide (posted 31-May-2013; official 01-Jun-2013)
* Verapamil Hydrochloride Extended-Release Capsules (posted 31-May-2013; official 01-Jun-2013)

Three New Interim Revision Announcements:

* Escitalopram Oxalate (posted 31-May-2013; official 01-Jul-2013)
* High Fructose Corn Syrup (posted 31-May-2013; official 01-Jul-2013)
* Tamsulosin Hydrochloride Capsules (posted 31-May-2013; official 01-Jul-2013)

FDA approves RFID-Enabled Blood Bag tracker

MedPage Today (5/30, Gever) reports that the US Food and Drug Administration on Tuesday announced it has approved Brookfield, Wisconsin-based SysLogic's iTrace, a "radio frequency identification tagging system" that uses "small memory chips placed on blood component bags and readers to download" data and store information on the contents in the bags and their expiration dates as well as other "collection and processing" details. The iTrace system "would be used alongside existing labels and barcode IDs, the agency said" in the announcement. FDA Center for Biologics Evaluation and Research Director Dr. Karen Midthun explained that the "iTrace for Blood Centers will be used in blood establishments by trained personnel as a tool in streamlining blood collection and processing and aiding in product tracking and reconciliation."

Lecture on

"Clinical Trial -What and Why"

By Dr Srirupa Pal
8th June Saturday at 6pm
in IPA Auditorium

Study reveals Physicians insufficiently informed of Drug Side Effects

An international study involving 255 physicians practising in Vancouver, Montreal, Sacramento and Toulouse found that physicians are not given enough information about the adverse effects of drugs during presentations made by medical sales representatives from pharmaceutical companies. And yet, these same physicians are willing to prescribe at least some of the presented drugs. Dr. Geneviève Durrieu (from the Pharmaco-epidemiology team assessing the use of medication and the risks involved, Unit 1027 "Epidemiology and public health analyses: risks, chronic diseases and handicaps" – Inserm / Université Toulouse III – Paul Sabatier) led the French part of this study, the results of which are published in the

Journal of General Internal Medicine. Within the framework of this international study, is France proving to be a model student?

Prescription-only drugs play a major part in the therapeutic care of the patient. However, they can also have adverse effects on the patient's health. Several studies have shown that the information provided by the medical sales reps strongly influence the decision to add a drug to a prescription, often without the physician being fully aware of the side effects. In order to find out more, international researchers carried out an accurate study on the quality of the information given by medical sales reps when promoting drugs to physicians.

4 sites were selected: Vancouver, Montreal, Sacramento and Toulouse. The physicians were selected by a draw. Of the 704 physicians contacted, 36% agreed to participate. Then information was gathered about 1692 drugs promoted by medical sales reps between May 2009 and June 2010.

After each visit from the sales rep, the physicians were asked to fill in a questionnaire about how the drugs were promoted by the sales rep: they gave information (benefits and risks) about each promoted product, handed out free samples and gave invitations to events.

An overall lack of information

In this study, the researchers reported that the information given by the medical sales reps concentrated on the benefits of the drugs presented more often than their potential risks.

And the same situation was reported for all sites in the study (Montreal, Sacramento, Toulouse and Vancouver). During more than half of the visits made to promote drugs (59%), the sales rep did not mention any adverse effects at all. This figure rose to 66% for Vancouver and Montreal. Even more worrying: the results showed that "serious" side effects of drugs were only mentioned in 6% of the sales promotions.

France may be a model student, but…..

France differs from other countries by the fact that that the risks are mentioned more often by the sales reps: in 61% of cases to be exact.

But the overall figure taking into account all the countries involved in the study gave an average of only 41%.

However, this figure must be considered with caution, because the information given mainly concentrated on frequent and benign side effects (such as nausea, diarrhoea), whereas, in the other sites, 94% of presentations mentioned no "serious" side effect whatsoever.

On the other hand, the therapeutic benefits are highlighted in 80% of cases.

Physicians are willing to prescribe promoted drugs

In this study and whatever the country, 2/3rds of physicians declared that the presentation would encourage them to prescribe a promoted product, or would "probably" or "very probably" incite them to prescribe this product more often.

What are the rules applicable to medical sales reps?

In France and in the USA, government authorities in charge of medication regulations are in charge of the rules and supervision of medical sales rep presentations at physicians' surgeries. In France an additional approach was introduced in 2005. It is known as the Charter of Ethics for Pharmaceutical Sales Visits. This charter sets out the authorized and the prohibited practices and the information that must be given to the physician.

In Canada, the medical sales rep visits are regulated by Canada's research-based pharmaceutical companies (Rx& D), who set out criteria concerning the information to be given to the physician.