Drug Information Bulletin

Drug Information Centre (DIC)

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Content

Editorial

Access to essential medicines is a problem throughout the globe especially in the developing and under developed countries. India is not an exception, where only 35-50 percent of its population has access to essential medicines, though India is the third largest producer of medicines and is exporting to about 200 countries.

It is estimated that 6 percent of GDP require to be spent on health but presently Government spending on health is about 1.04 percent and it has been proposed in the draft of National Health Policy to spend more in health.

Though a small fraction of our population is covered by govt. sector health facilities and mostly depends on private health care facilities.

Experts believe there are several complex reasons behind poor accessibility. One of them is irrational use of medicines. Prescribing in generic name is considered as one of the important tools for improving rational use of medicines.

In India Central Government, several State Governments and some agencies have instructed the doctors under Govt. sector to prescribe in generic name but unfortunately it has not been strictly implemented.

It was noticed that recently a few state Governments have taken stringent measures for its implementation. It is expected that it may bring tangible change in improving accessibility.

Dr. Subhash C. Mandal
Editor

USP–NF. Compendial Update

On 30th January 2015 the US-NF announced Six New Revision-

- Desoxycorticosterone Pivalate Injectable Suspension (posted 30-Jan-2015; official 01-Feb-2015)
- Fosphenytoin Sodium Injection (posted 30-Jan-2015; official 01-Feb-2015)
- Ketorolac Tromethamine Tablets (posted 30-Jan-2015; official 01-Feb-2015)
- Oxycodone Hydrochloride Oral Solution (posted 30-Jan-2015; official 01-Feb-2015)
- Potassium Citrate Extended-Release Tablets (posted 30-Jan-2015; official 01-Feb-2015)
- Trazodone Hydrochloride (posted 30-Jan-2015; official 01-Feb-2015)

For details: http://www.usp.org/usp-nf/notices

Current Good Manufacturing Practice Requirements for Combination Products: A new Rule by US FDA published on 22.01.2015

The Food and Drug Administration (FDA or Agency) is issuing this regulation on the current good manufacturing practice (CGMP) requirements applicable to combination products. This rule is intended to promote the public health by clarifying which CGMP requirements apply when drugs, devices, and biological products are combined to create combination products. In addition, the rule sets forth a transparent and streamlined regulatory framework for firms to use when demonstrating compliance with CGMP requirements for "single-entity" and "co-packaged" combination products.

For details: https://www.federalregister.gov/

A new index measures impact Pharma has on infectious diseases

The pharmaceutical industry regularly boasts that its efforts to develop treatments for infectious diseases in poor nations are making a difference. But for those wondering how to gauge those efforts, a new metric has been created.

The Global Health Impact Index measures three factors: the need for several important drugs for three specific infectious diseases: tuberculosis, HIV/AIDS and malaria; the effectiveness of the available treatments; and the number of people who can access those drugs. The rankings estimate the amount of death and disability the drugs are alleviating.

So how did drug makers fare? Of 16 companies that were evaluated, Sanofi ranked highest, followed by Novartis and Pfizer. Kyorin Pharmaceutical garnered the lowest rating, with Bayer and Eli Lilly LLY -0.15% not far behind. We asked the drug makers for comment and will pass along any replies.

The index arrives as more pressure is being placed on drug makers to meet the needs of poor populations. In response, various companies have crafted deals with government agencies and public-private partnerships to bolster development, production and distribution. But while there may be sufficient data available to track the need for such medicines, there is currently no way to determine the extent to which drug makers and their products are having a desired effect, according to Nicole Hassoun, an associate philosophy professor at Binghamton University, who developed the index.

"By better understanding the impacts of products on the burden of disease, the index gives researchers a tool for measuring impact, governments and donors can better target their efforts and companies can be incentivized to focus on impact," she writes us in an e-mail.

There is another tool out there called the Access to Medicines Index, which assesses such factors as patenting policies, price reductions, involvement in public-private partnerships and charitable contributions. But Hassoun contends this doesn't guarantee what she terms a good outcome.

By contrast, she hopes the index she devised can serve as the equivalent of a Good Housekeeping seal of approval. The idea is that highly rated drug makers would have incentive to promote their rankings on their products which, presumably, would appeal to consumers and healthcare providers.

As Hassoun sees it, such a system would foster more interest in corporate social responsibility and, perhaps, serve as a model for policy makers seeking to improve access to a variety of medicines, not just those for infectious diseases.

Such indices "encourage competition among biopharmaceutical companies, and they motivate us to improve our contribution to public health," says Francois Bompart, a Sanofi vp in charges of access to medicines.

A Lilly spokesman points out the drug maker does not sell any medicines for those three infectious diseases, but through foundation support has given away trademarks and manufacturing technology for two TB medicines, and launched a public-private partnership to discover TB drugs.

And a Pfizer spokesman sends us a note to say the drug maker "shares the goals of projects like these to measure activities and programs that improve access to medicines for people who need them."

Source: http://blogs.wsj.com/pharmalot/2015/01/23/a-new-index-measures-impact-pharma-has-on-infectious-diseases/

Obama proposes increased funding to combat antibiotic-resistant bacteria

President Barack Obama will request $1.2 billion in his budget proposal to better monitor and treat antibiotic-resistant bacteria. Under the proposal, the NIH and the Biomedical Advanced Research and Development Authority would receive $650 million to develop new drugs and diagnostics. The CDC would receive $280 million for disease tracking of outbreaks of drug-resistant infections, and the FDA would receive $47 million for new drug reviews and livestock monitoring.

Source: The Washington Post

Africa's First Insulin Factory

Julphar Pharmaceutical expands existing factory to create an insulin factory with aim to make Ethiopia the insulin hub of Africa.

Mukemil Abdella, country director of Julphar Pharmaceutical Industry did not specify the production capacity of the plant, only saying that the company aimed to make Ethiopia the insulin hub of Africa by reaching across the continent. The Ethiopian side of the company, Med-tech Ethiopia, is a privately owned pharmaceutical and medical supplies importer and distributer. It has a 45pc share in the company, with Julphar Ethiopia Pharmaceutical, holding the majority share.

For details: http://addisfortune.net/articles/africas-first-insulin-factory/

MHRA issues GMP data integrity definitions & guidance document for pharma cos

The UK's Medicines and Healthcare Products Regulatory Agency (MHRA) recently released its GMP data integrity definitions and guidance document for the pharma industry. This document consists of MHRA's expectations from the

pharma companies while dealing with the matters on data integrity.

This move further strengthens and highlights the importance regulatory agencies are giving to the compliance of data integrity as a fundamental element in ensuring the quality of the medicines. It is understood that this guidance is intended to complement existing EU GMP, and should be read in conjunction with national medicines legislation and the GMP standards.
Interestingly, MHRA from the start of 2014 had directed all the pharma manufacturers, importers and contract laboratories, as part of their self-inspection programme, to review the effectiveness of their governance systems to ensure data integrity and traceability, in accordance with Chapter 9 of EU GMP.

It was also expected that in addition to having their own governance systems, companies outsourcing activities should verify the adequacy of comparable systems at the contract acceptor. Highly placed source from the industry stressed that by coming out with this guidance document, the MHRA has established the importance it gives to data integrity and their future course while examining a case.
The source pointed out that now while the industry does have a reference point to clarify their doubts, lack of sensitisation among the stakeholders on the importance of complying to the same needs to be addressed to avoid complication.

In the recent past, Indian pharma companies had been increasingly getting unwanted attention from the international drug regulatory agencies like US FDA due to various data integrity issues. They have repeatedly questioned Indian companies' ability to demonstrate the integrity and security of laboratory data, records, results and information are prerequisites for any successful inspection of any GMP regulated quality control laboratory.

Kaushik Desai a senior industry expert, stressed that this is a strategic move by the MHRA aimed at guiding the industry to understand and incorporate data integrity for ensuring quality. If taken in stride, this guidance document can go a long way in understanding the complex system of the data integrity procedures and utilising it within the organisation.

The document elucidates that the data governance system should be integral to the pharma quality system described in EU GMP. As such, manufacturers and analytical laboratories are not expected to implement a forensic approach to data checking, but instead design and operate a system which provides an acceptable state of control based on the data integrity risk, and which is fully documented with supporting rationale.

It is understood that the data integrity requirements apply equally to manual i.e paper and electronic data. Their guidance document states that manufacturers and analytical laboratories should be aware that reverting from automated or computerised to manual or paper-based systems will not in itself remove the need for data integrity controls.
Source: Pharmabiz

Forthcoming Event

National Workshop
on
Ensuring Quality through Good Laboratory Practice
Date: 8th March 2015 (Sunday)
Venue: Flotel, Kolkata
Organized by: RAD, IPA
Jointly with IPA, Bengal Branch