Drug Information Bulletin

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Content

Editorial

Indian Pharmaceutical Industry is 3rd largest by volume and exporting huge amount of pharmaceuticals worth of INR 47551 crores (2010-2011) and supplying medicines to more than 200 countries and vaccines to more than 150 countries, which involves both developed and developing countries. Highest importer is USA and 2nd highest is UK.
According to the Medicines and Healthcare Products Regulatory Agency (MHRA), UK has licensed Indian factories to produce the finished form of 3,685 drugs compared with 3,815 made within the UK. This fact shows the strength of Indian Pharmaceutical Industry.
Recently a few Indian industry received warning from both the USA & UK, which is important but not alarming considering the volume of export to these countries from India.

It is evidenced by the statement of Gerald Heddell, director of inspections, enforcement and standards at the MHRA that the number of problems identified by regulators in India was in proportion to the volume of medicines they produced.

Projects set to tackle neglected diseases

Kala-azar, the most deadly parasitic disease after malaria, afflicts hundreds of thousands of the world's poorest people in tropical countries such as India, Brazil and Sudan. Spread by sandfly bites, the disease can be fought with existing treatments — but these are expensive and inconvenient, and sometimes have toxic side effects.

Yet commercial work aimed at finding better drugs for kala-azar has largely been abandoned. Pharmaceutical companies say that poor customers cannot afford to pay the high prices needed to recoup development costs. Critics say that eight proposals, endorsed last month by reviewers for the World Health Organization (WHO) to break the stalemate for this and other neglected diseases, are noble, but no solution. The measures will do little, they say, to solve a broader problem: the disparity in spending on research and development for diseases of the rich and those of the poor.

The proposal to combat kala-azar (also known as visceral leishmaniasis, or VL) would combine groups already working on drugs for the disease into a single organization, the VL Global R&D & Access Initiative. This would seek to develop durable oral drugs that do not require cold storage or intravenous delivery. The non-profit plan will be considered by the WHO executive board at a meeting on 20–25 January at the organization's headquarters in Geneva, Switzerland.

But critics are upset that novel and more risky ideas that would have helped to unlink the cost of drug development from prices were eschewed in favour of the eight shortlisted proposals, which were seen as more viable because they build on existing efforts and focus on specific diseases. "The proposals that were brought forward were not as strong as we had hoped in identifying alternative pathways to traditional research and development through commercial channels," says Nils Daulaire, assistant secretary for global affairs at the US Department of Health and Human Services. "That was, frankly, disappointing."

In response to this criticism, the WHO has asked the backers of the eight projects — five of which focus on developing vaccines or medicines for specific neglected diseases, one on fever diagnostics and two on basic research — to explain this month how they will test methods for funding the work. The responses will help the executive board to decide which projects to endorse. Then, at a World Health Assembly meeting in Geneva in May, countries will be asked to commit funds for the schemes.

The projects are part of an attempt to salvage a decade-long effort to create new funding mechanisms for neglected diseases. Despite campaigning from advocacy organizations such as the Drugs for Neglected Diseases Initiative in Geneva, and hefty donations from groups such as the Bill & Melinda Gates Foundation in Seattle, Washington, drug development is still disproportionately focused on diseases of the rich, such as heart disease and cancer.

Three times in the past decade, countries have failed to sign treaties that would commit them to fund drug development for neglected diseases. When the latest attempt was quashed in November 2012, diplomats agreed instead to back a series of demonstration projects that would test new funding mechanisms and be reviewed in 2016.

But critics worry that the eight shortlisted pilot projects are not actually testing new ways of funding, and that more innovative ones have been shelved. One proposal, rejected last month, would have used two tools — milestone payments and patent pools — to spur the development of tuberculosis medicines. Milestone payments would reward early-stage successes of potential drugs, such as proof of activity in humans. Recipients of the payments would then place intellectual property on these potential drugs into a patent pool. Drug developers could license these patents at low cost and would agree to put further patents back in the pool. Another rejected proposal involved taxing antibiotic use to fund the development of antimicrobials.

In their deliberations, reviewers were asked to score the projects' public-health impact and scientific merit ahead of their novelty. Some neglected-disease advocates say that those priorities should have been reversed. Now that the more innovative projects have been dropped, "we're not going to get to the place in

two years' time where we can say how well a completely different approach to research and development can work", says Katy Ather such, an advocate for affordable medicines with the non-profit organization Médecins Sans Frontières (also known as Doctors Without Borders), based in Geneva.

Paying for the projects in the traditional way — by garnering direct support from donor nations — may be difficult enough. A 2012 WHO report recommended that all countries spend 0.01% of their annual gross domestic product on neglected diseases, which would roughly double spending on these illnesses to US$6 billion per year. Only the United States is currently doing this, and emerging economies such as China, Brazil and India have yet to increase their spending.

If the WHO endorses some of the eight projects later this month, it will be a critical time to see if nations step up to pay for them, says John-Arne Roettingen, a global-health researcher at Harvard School of Public Health in Boston, Massachusetts. He says: "This will be the first test of whether countries are willing to put their money on the table."

For details: http://www.nature.com/news/projects-set-to-tackle-neglected-diseases-1.14474

Global reach of India drug producers grows

India is producing almost as many medicines for the UK as those manufactured within Britain itself, according to figures showing the growing influence of Asia in the global pharmaceuticals market.

Data from the Medicines and Healthcare Products Regulatory Agency, the London-based medicines watchdog, show it has licensed Indian factories to produce the finished form of 3,685 drugs compared with 3,815 made within the UK.

They place Indian companies far ahead of all other foreign producers for British patients - led by companies in Germany, Ireland and France - and reflect estimates that its fast-growing manufacturers are responsible for a quarter of all medicines consumed in the country.

While India has long produced raw materials and the "active pharmaceutical ingredients" to supply others making finished medicines, the statistics show the country's expansion as fully fledged producers.

The British statistics mirror high and rising penetration rates by Indian producers in other industrialised countries around the world and have raised some concerns over quality as manufacturing shifts beyond national boundaries.

Two large Indian generic drug producers - Ranbaxy, owned by Daiichi Sankyo of Japan, and Wockhardt - in recent months received US and UK regulatory bans respectively on the import of some of their products following quality concerns including fabrication of tests on their ingredients.

However, Gerald Heddell, director of inspections, enforcement and standards at the MHRA, stressed that the number of problems identified by regulators in India was in proportion to the volume of medicines they produced.

"When we look back over 110 inspections we conducted over the last two years in India, we had significant concerns with 9 or 10 companies," he said. "That does not represent a statistically higher proportion than in other parts of the world. India stands out because it is just such a big supplier."

Arun Sawhney, Ranbaxy chief executive, stressed his co-operation with US regulators in meeting their requirements including the lifting of a ban on some products.

"The global pharmaceutical landscape is changing and we have to change with it," he said.

"The expectations of regulatory agencies all over the world are increasing and clearly, we have to continue to raise the standards of our processes to be ahead of these changes.
"We are certain that the efforts under way in this regard will enable us to emerge stronger in our standards of quality and compliance."
Although most Indian pharmaceutical companies make off-patent generic drugs, they also supply products to those making innovative medicines.
A separate analysis conducted by Withers & Rogers, a legal firm specialising in intellectual property, showed an increase from 160 to 450 annual patent filings by Indian companies over the past decade.
However, most have been technologies such as manufacturing processes for existing drugs, new formulations and crystalline forms rather than the development of novel compounds.
http://www.ft.com/intl/cms/s/0/924831be-75e9-11e3-8c8d-00144feabdc0.html?siteedition=intl#axzz2pVabyoo9

Abbott faces serious recall of Diabetes products

FDA has recently given Class I status to a recall of Abbott Laboratories' FreeStyle and FreeStyle Lite test strips, which indicates that the products could cause serious injury or death. Abbott voluntarily recalled the strips because they were found to provide inaccurate readings of blood glucose when used with the FreeStyle and FreeStyle Flash meters and the Insulet OmniPod. The FreeStyle and FreeStyle Flash devices have not been produced since 2010.
In a press release, Abbot explained that the problem in question did not occur with its newer FreeStyle Freedom, Lite and Freedom Lite meters. However, by possibly producing inaccurately low test results for blood glucose levels, the FreeStyle and FreeStyle Lite test strips could raise a diabetics' risk of hypoglycemia, which can lead to unconsciousness, seizures, or death in severe cases.
Abbott announced the recall of 20 lots of the two FreeStyle-branded test strip lines on 27 November 2013.
The company also had an earlier Class I recall of its FreeStyle InsuLinx meters in the spring, which were found to work incorrectly with abnormally high blood glucose levels.
Ref. Qmed.com

Forthcoming Event:

Annual Picnic of IPA Bengal Branch
Venue:
Pujali Guest House,
Date:
19th January 2014(Sunday)
Contact:
Mr. Asit Roy- Mob.9831706765
Mr. Pradip Kumar Mallik-Mob. 9830574612
Mr. Indrajit Kar – Mob.9433660607
Dr. Mukti Pada Rana – Mob.9433015483
Mr. Madhab Banerjee - Mob.9748674625

Health Camp
At Gangasagar, Dist. 24 pgs (south)

Date:
10th January 2014 - 15th January 2014

Organized Jointly by:
Indian Pharmaceutical Association, Bengal Branch
&
IPA Bengal Pharma & Health Care Trust