



# Drug Information Bulletin

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*Indian Pharmaceutical Association*

*Bengal Branch*

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## Editorial

Role of Pharmacist as a health care professional expanded through the MOU signed by IPA, SEARPharm Forum, PCI, AIOCD and Central TB Division - Govt. of India with an objective to strengthen the Revised National Tuberculosis Control Programme (RNTCP) by engaging pharmacists in RNTCP for TB Care & Control in India. Engaging Pharmacists' in TB programme was initiated in Mumbai by Indian Pharmaceutical Association (IPA) in the last decade through a pilot programme which was implemented some other states of India. This model was successful and several countries expressed to follow this model in their country. In the mean time WHO signed a MOU with FIP on the role of Pharmacists in Tuberculosis care and control in the year of 2011 during FIP Congress at Hyderabad, India. Thereafter SEARPharm Forum has published a document "Compilation of a reference document of pharmacists innovative approaches to target early detection, delivery of dots, rational use, public education in TB care and Control in India [http://www.searpharm.org/resources/PDF\\_files/REPORT%20final.pdf](http://www.searpharm.org/resources/PDF_files/REPORT%20final.pdf) . In order to engage community pharmacists in Tuberculosis care and control under RNTCP a training module has been developed jointly by Central TB Division, Govt. of India and Indian Pharmaceutical Association and published it in the year of 2013. This initiative is a unique one in expanding the scope of pharmacist's role in health care system in India [www.tbcindia.nic.in/pdfs/MODULAR%20TRAINING%20a.pdf](http://www.tbcindia.nic.in/pdfs/MODULAR%20TRAINING%20a.pdf) . This unique opportunity should be utilized properly by the Pharmacists and pharmaceutical professional organizations in India.

## EU approved SC Injectable of Trastuzumab

Roche announced that a new injectable (subcutaneous) formulation of Herceptin (trastuzumab) has been approved by the European Commission for the treatment of HER2-positive breast cancer, an aggressive sub-type of the disease. The approval is for both early and later stages of treatment.

According to Roche more than 90,000 women in Europe are diagnosed with HER2 positive breast cancer every year and this formulation of Herceptin may enable patients to spend less time in the hospital and more time getting on with their lives.

Research shows that maintaining a normal life and spending time with friends and family can improve the wellbeing of women with breast cancer. The new formulation may reduce the amount of time patients spend in hospital receiving treatment with Herceptin as it can be administered at least six times faster than the standard intravenous form.

The European Commission's approval was based on data from the HannaH study which showed that the subcutaneous formulation of Herceptin was associated with comparable efficacy (pathological complete response, pCR) to Herceptin administered intravenously in women with HER2-positive early breast cancer and resulted in non-inferior trastuzumab plasma levels. Overall, the safety profile in both arms of the HannaH study was consistent with that expected from standard treatment with Herceptin and chemotherapy in this setting. No new safety signals were identified.

## \$1.6bn needed annually to fight drug-resistant TB -WHO, Global Fund

With the drug-resistant forms of tuberculosis (TB) still a global health crisis and the number of persons receiving multi-drug resistant tuberculosis (MDR-TB) treatment globally remaining low, the World Health Organization (WHO) and the Global Fund identified a funding of US\$ 1.6 billion annually is needed for the treatment and prevention of tuberculosis in 118 low and middle income countries, including Nigeria.

On top of an estimated US\$ 3.2 billion that could be provided by the countries themselves, filling this gap would enable the treatment for 17 million TB and multidrug-resistant TB patients and save six million lives between 2014 to 2016.

As the epidemic continues to spread, drug-resistant TB becomes increasingly hard to tackle with the treatment been too long, too toxic and too costly. The drugs, according to BusinessDay findings, cost at least \$4,000 just to treat one person.

Margaret Chan, director general, WHO and Mark Dybul, executive director, Global Fund, stated that the only way to carry out urgent work of identifying all new cases of tuberculosis, while simultaneously making progress against the most serious existing cases, would be to mobilise significant funding from domestic sources and international donors.

With an overwhelming majority of international funding for tuberculosis coming through the Global Fund, they stressed the need for effective efforts to raise money in 2013.

"We are treading water at a time when we desperately need to scale up our response to MDR-TB. We have gained a lot of ground in TB control through international collaboration, but it can

easily be lost if we do not act now," Chan said.

Lending his view, Dybul said that "It is critical that we raise the funding that is urgently needed to control this disease. If we don't act now, our costs could skyrocket. It is invest now or pay forever."

Globally, MSF projects are seeing unprecedented numbers of people with MDR-TB with drug resistance found not only among patients who have previously failed TB treatment but also in patients newly diagnosed with TB; a sign that MDR-TB is being transmitted.

Left untreated, the infectious disease is lethal, but treatment today puts people through two years of excruciating side effects, including deafness and constant nausea, with painful daily injections for up to eight months.

While the Millennium Development Goal of turning around the TB epidemic has already been met, the two percent decline in the number of people falling ill with TB annually remains too slow. Two regions-Africa and Europe, are not on track to achieve the global target of halving the TB death rate between 1990 and 2015.

In 2011, 1.4 million people died due to TB, with the greatest per capita death rate in Africa. Multidrug-resistant TB (MDR-TB) presents a major threat, with an estimated 630,000 people ill worldwide with this form of TB today.

WHO worked with the Global Fund and the Stop TB Partnership to support selected high TB burden countries in reviewing their priorities for the next three years and estimating available funding and gaps. Estimates have been made for 118 countries eligible for Global Fund support.

Of the US\$ 1.6 billion gap in donor financing, almost 60 percent is for WHO's

African region. In the 118 countries, there are four priority areas for domestic and international investment-to drive down deaths, alleviate suffering, cut transmission and contain spread of drug resistance.

Reference: Business Day

### **China alleges that GSK organized bribe scheme**

China's state-owned Xinhua news agency reports that, contrary to what GlaxoSmithKline has said, bribery of hospital officials and physicians was organized at the company level and was not simply the actions of unauthorized individuals. The Xinhua story stated that GSK units for large customers kept more than \$1.6 million in "public relations funds" to dispense to key hospital personnel. One senior GSK China official said that the company pressed for annual growth rates as high as 25%, which is 7% to 8% higher than the industry average.

Ref. PharmaTimes (U.K.)

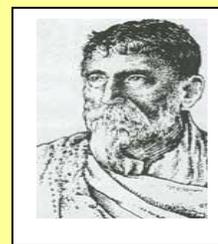
### **Regulatory issues hinder clinical trials in India**

Regulatory uncertainty and clinical trial policies are hindering drug research and development in India, according to a 2013 McKinsey report for the USA India Chamber of Commerce. Data analysis shows that of approximately 120,000 worldwide clinical trials, 90% are taking place in North America or Western Europe, compared to 2.2% in India and 2.83% in China. The number of approved clinical trials in India has dropped steadily, from 500 in 2010 to 262 in 2012.

Ref. BioSpectrum Asia

## Recommendations for Acharya P. C. Ray Memorial Gold Medal Award, 2013 invited

The Indian Pharmaceutical Association, Bengal Branch gives annually gold medal on the occasion of celebration of National Pharmacy Week during 3<sup>rd</sup> week of November of each year to perpetuate the memory of great national figure Acharya P.C.Ray, the pioneer designer of Pharmaceutical Industry in our country since 1962.



IPA, Bengal Branch Council select the awardee amongst the Pharmaceutical Scientists, Teachers, Pharma Regulators, Hospital Pharmacists, Community Pharmacist, Administrators, etc. for outstanding contribution in their respective field and for overall development of the profession of pharmacy.

Any member of IPA can recommend name of the person with their detailed Bio-data & Two Page summary of the Bio data for 2013 award, which may be sent by 15<sup>th</sup> October 2013 to:

**The Hony. Secretary,**  
Indian Pharmaceutical Association, Bengal Branch,  
22 B Panchanontola Road,  
Kolkata – 700029  
e-mail: [ipabengalbranchn@gmail.com](mailto:ipabengalbranchn@gmail.com)

### **N.B.: Biodata should include the following points-**

1. Date of Birth.
2. Qualification.
3. Experiences in the selected field.
4. Achievements in advancement of sciences/Administration/relevant field.
5.
  - a. Whether member of IPA? If yes, how many years?
  - b. Whether member of allied pharmaceutical profession other than IPA? If yes, how many years?
6. Services rendered (in years) on the executive Council of IPA Centre or any of its Branches in the capacity as:
  - a. President/Vice President/Hony. Secretary/Treasurer/Editor of Official Publication of IPA.
  - b. Executive Council Member.
7. Recognition/Award received from other professional organizations including industry/trade associations.
8. Award/Recognition/Honour received from international/national Govt. authorities or prestigious institution/organization by way of award or membership of their constituted body/committee other than sl. No. 6 above.
9. Performance in growth/ improvement of any of the field of pharmacy and shown creditable leadership in the chosen field.
10. Involvement and outstanding achievements in professional development in national/international arena.
11. Notable achievements in any other field or profession excluding pharmacy for which the nominee is nominated for the award including social welfare activities with Govt. and Non Govt. organizations.