

## 2014 holds new promise for India

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The year 2013 was probably one-of-the-worst years for the Indian economy as economic growth decelerated to below five percent and inflation soared. Political bickering and scandals kept the government in fire-fighting mode, leading to a stalling of much-needed economic reforms and policy paralysis.

The extent of the government's failure was reflected in the skyrocketing prices of onions, despite India being the world's second-largest producer of onions after China. In order to manage this manmade crisis the Indian government was compelled to import onions from neighboring countries. It is no wonder then that elections in India are fought over rise and fall of 'vegetable prices.' Trouble for pharma industry India's pharma sector also witnessed an unprecedented slowdown, growing at barely 5.20 % in 2013 against an average growth of 12 percent the previous year. The negative impact was further compounded by adverse policy decisions in India with respect to a new drug price control regime, a moratorium on clinical trials, uncertainty trol regime, a moratorium on clinical trials, uncertainty over the FDI policy and attempts to invoke frivolous compulsory licenses on several drugs.

An overactive US FDA did not help matters, as it hauled up several leading Indian pharma companies for non-compliance. All these negative developments collectively turned 2013 into an Annus Horribilis for the Indian pharma sector.

### **The good news**

It was not all gloom and doom. On the brighter side, India took the lead in developing and adopting biosimilars guidelines, which enabled the approval of the world's first biosimilar of Herceptin for breast cancer, developed in India by Biocon and

Mylan.

The introduction of biosimilar Trastuzumab in India in 2014 will offer an affordable option for millions of cancer patients in India and in the other world markets subsequently.

### **What to expect in 2014?**

As 2014 is an election year, we can expect the general elections to lead to a stable majority government at the Center. Hopefully, that will be a starting point for addressing some of the country's long-pending challenges through bold policy reforms.

We hope that the new government will be able to create real jobs, provide good infrastructure for industrial growth, facilitate ease of doing business in the country, ensure safety and security for women and promote better governance.

At the same time, the government will need to come up with innovative solutions to meet the burgeoning healthcare needs of the country's teeming millions through affordable medicines.

One of the ways to do this is to define a smarter regulatory pathway. Indian regulators can ensure improved access to affordable drugs by ensuring that local regulatory requirements don't add to the cost of drug innovation and force innovator companies to price their products at a premium.

Indian companies, on their part, will need to take swift corrective action to address issues of non-compliance with globally accepted manufacturing norms and regain their reputation as quality producers of affordable generics for global markets.

The industry now needs to ensure that it has rigorous processes for self-audit to ensure zero tolerance to non-compliance. The new pharma pricing policy has led to a lot of confusion in the market with the result that some drugs have become unavailable, hurting patients. Hopefully, 2014 will see the current issues being ironed out and patients ultimately benefiting from the transition to the new pricing regime.

However, the government can't expect the industry to bear the full burden of making medicines affordable, while abdicating its responsibility towards public health. The government should speedily come out with a policy for universal healthcare coverage to address the needs of the poor.

If India wants access to cutting-edge pharma products from overseas innovators it is imperative that clinical trials are conducted to find their suitability for the Indian population.

Therefore, the Indian government and courts should tackle the issue of clinical trials with a rational understanding of the benefits and with greater compassion for those suffering for want of effective medicines.

For Biocon, 2014 holds good promise as we bring the world's first biosimilar Trastuzumab to cancer patients in India, our novel biologic Alzumab makes a positive impact on the lives of thousands of psoriasis patients, our Malaysia plant nears completion and all our business verticals continue to report robust growth.

Year 2014, can be a year of positive change if every citizen of India commits to engage with the political process, plays the role of a responsible citizen and demands good governance. Citizen participation is critical for creating an economically strong India that can gain global recognition.