PHARMACEUTICAL R&D : IS THE PIPELINE RUNNING DRY – EXPLORING THE ALTERNATIVES

I. Is R&D Pipeline Running Dry?

- The answer to the first part of the question is yes; the Pharmaceutical R&D pipeline is getting depleted.
- The Economist (30th June, 2007) reports that, in 1995 in North America, against a spending of 15 Bn. U.S.$, 54 NCEs got FDA approval. Against that in 2006, against an R&D spend of 22 Bn. U.S.$, only 43 NCEs got FDA approval.
- It is reported that R&D costs have skyrocketed 23-fold in the last 28 years touching an all time high of 1.25 Bn. U.S.$ / NCE.
- Drug development time has also gone up significantly from around 10 years in the 1970s; one of the key reasons is stringent regulatory requirements and rightly so.
- This is reducing market life of a NCE shaving billions of potential revenues.
- It is true that R&D pipeline is thinning – more blockbusters set to go off-patent than to emerge from R&D pipeline.

Thus,

II. Global Pharmaceutical Industry Challenges:

- Decreasing R&D output to increasing R&D time
- Increasing R&D costs
- Generic competition price pressure

III. **Exploring Alternatives:**

- To address this issue, India becomes a hub of choice to reduce R&D costs and time through collaborative work:

  (1) R&D outsourcing

  (2) Outsourcing clinical development

- Probable future scenario, more collaborative work for both research and development between Indian companies and the MNCs. However, Indian companies will continue to compete with MNCs in the global generic market.

IV. **Advantage India:**

- Clinical studies take between 30-50% of the time spent in R&D and within this a third of the time in clinical trials is taken in patient recruitment.

- Both cost and duration of clinical trials can be greatly reduced in India

  (A) India is the second most populous country in the world with a large pool of naïve patients and fourth largest pool for medical professionals in the world.

  (B) Rapidly improving support industries and world respected IT industry to support R&D and clinical trials.

  (C) India offers over 700,000 speciality hospital beds at about $1/10^{th}$ of the price of developed nations.

  (D) Over 220 medical colleges and skilled English speaking medical personnel.

  (E) Contract research and clinical development business in India will grow from 59.4 Mn. U.S.$ in 2003-04 to around 500 Mn. To 1 Bn. by 2010 (optimistic estimate), 250 to 300 Ms. (pessimistic estimate)

V. **Disadvantage India:**

A. **Infrastructure / Facilities and other issues** –

- Against the number of GCP trained investigators of over 40,000 in the US, in India this number will be around 300.
- Most clinical trial studies are carried out in 25-30 major public hospitals in major cities.

B. **IT vs. Pharmaceuticals** – (over-regulated)

- Pharmaceutical Industry faces quite a few challenges before it can claim to be of world class status like the IT industry.
- IT industry flourished because it was under-regulated; in contrast, Pharmaceutical industry is over-regulated.
- Import of body fluids / test samples from India has been another bottleneck.
- Ethical trials is another issue. There are instances of litigation for unethical trials without requisite permissions or on ill-informed patients.
- Local disinformation campaign can also mar clinical trials status and damage company reputation.

C. **Robust IPR Regime** –

- Although Indian Patents Act (Amendment) 2005 is in place, there are still some key concerns in the following areas:
  - Patentability
  - Pre-grant Opposition
  - Regulatory Data Protection
  - Compulsory Licensing
  - Patent Enforcement

VI. **Conclusion:**

- To explore the alternatives, it appears that outsourcing clinical development and contract research will help address some of the key challenges towards R&D pipeline running dry.
- Benefits in terms of time and cost savings to the global players are too significant to ignore.
- Some estimates show that average saving per commercialized drug can be upto an optimal over 350 Mn. U.S.$.
- However, in these areas main competition will come from China. Already in the clinical trials area, China is much ahead of India (China 419 and India 376)

Thus, I strongly recommend and expect that the global research based pharmaceutical companies will explore these alternatives to meet the unmet needs of the patient and at the same time remain commercially healthy and competitive.

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