

Clinical test data exclusivity and Access to medicines in India

Clinical test data

- Clinical test data are the results of trials designed to gauge efficacy, safety and toxicity of a drug
- Clinical trials cost money; however only one set of trials is conducted to approve a drug anywhere in the world

The furore

- MNC pharmaceutical companies are asking that their data is made “exclusive” – i.e. used to prevent legitimate generic entry – for a period of 3 to 10 years after submission
- This is called “Data Exclusivity” – it is TRIPs plus (i.e. TRIPs does not ask for it)

The situation in India

- At present, India does not fully protect the confidentiality of clinical test data as required by Article 39.3 of TRIPs
- However, India also does not provide exclusive rights over clinical test data

Problem/ Solution

- From the point of view of local patients and the local pharmaceutical industry (generics) an ideal solution would have been to implement “Data Protection” – i.e. adequate confidentiality to comply with TRIPs
- Data Protection is TRIPs compliant; it is also the ideal policy for Indian patients and companies

But...

- In 2007, the Satwant Reddy Committee released a report recommending next steps around clinical test data protection in India
- The committee's recommendations? First, data protection, and then, after an unspecified "transition period" – data exclusivity

The MNC perspective

- Clinical test data costs between \$100 - \$150 million to generate per drug
- This cost should be spread around the world, so countries like India should cough up and pitch in

The Indian perspective

- Developed countries account for over 90% of the MNC pharmaceutical industry's turnover
- Countries like India are relatively insignificant, accounting for between 0.5% and 1% of this turnover
- Moreover, India is emerging as a destination for clinical trials outsourcing, which will eventually result in cost reductions of up to 50%

The Indian perspective

- Of the top 20 drugs in the world in 2006, only 6 were actually sold in India by the MCN “originator” – so the MNC pharmaceutical industry has never seriously considered India as a market anyway

The Indian perspective

- Of all the “new” drugs (New Molecular Entities) approved by the US FDA between 2005 and the present, 87% of them have patents which would likely be invalid in India under our 2005 amended patents act

The Indian perspective

- Drug research and innovation has adequate incentive in India due to the introduction of product patents in 2005, and since the cost of bringing a new drug to market always includes the cost of clinical trials it is unclear as to why this requires any separate incentives

The road ahead

- Data exclusivity, as recommended by the Satwant Reddy Committee will prove to be disastrous to Indian patients and the domestic pharmaceutical industry
- There is absolutely no basis for it, either in international obligations or domestic policy concerns

The road ahead

- Oppose the introduction of data exclusivity
- Promote the introduction of minor changes to provide minimal data protection

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