Health Ministry's nod to WHO for a study on data exclusivity raises concern

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In a contradictory action, the Union Health Ministry, which had earlier opposed data exclusivity and had refused to sign the Satwant Reddy report in this connection, has recently given its nod to the World Health Organization (WHO) to commission a study on the ‘impact of Satwant Reddy Committee Recommendations on the Indian Pharmaceutical Industry’.

The union health ministry's move has raised eyebrows among the patient community and the public interest groups in the country as they view that data exclusivity could prevent the registration of low cost quality generic versions of medicines even when there is no patent on a medicine, when a drug does not meet the standards for patentability.

According to experts, the Health Ministry's views submitted to the Satwant Reddy Committee generally reflected the points that countries are not obligated under Article 39.3 to confer exclusive rights on the originator of test data in terms of fixed time period; the government should guard against any provision, which is either TRIPS plus or Article 39.3 plus; and while giving market approvals to drugs and pharmaceutical products the competent regulator (i.e. Drug Controller General of India) relies on bio-eqivalence and bioavailability data. Such reliance cannot be termed as 'unfair commercial use' in the context of Article 39.3.

There is suspicion among the public interest groups on the objective of the health ministry's latest move on the issue as they ask, why was the study commissioned if they did not agree with the report? And they are all the more suspicious on whom the study has been commissioned to. The study has been commissioned to Pravin Anand of Anand and Anand (law firm) who was a member of the Satwant Reddy Committee and has in different forums expressed his views on Article 39.3 that it obligates India to implement data exclusivity.

In addition this law firm also legally represents MNCs who favour data exclusivity. The public interest groups have also raised concern over the
questionnaires for this study which, they suspect, are clearly designed to elicit a response that would justify the implementation of data exclusivity in India.

Considerable debate has been going on since 2005 (a few months after India implemented a product patent regime) on whether Indian should implement data protection or data exclusivity and the Indian government has been under considerable pressure from PhRMA and OPPI to implement data exclusivity based on their interpretation of Article 39.3 of the TRIPS Agreement-- to effectively delay the market authorization of generic medicines.

Data protection is non-disclosure of clinical trial data to third parties. This according to WHO will be TRIPS compliant and at the same time will not interfere with the work of a government body (the drug regulator) if he/she relies on clinical trial data to approve of affordable generic essential drugs. Data Exclusivity is a certain length of time during which the regulatory authority is prohibited from relying on the available clinical trial data in order to register a generic version of the same product.