

## Data Exclusivity

### What is data exclusivity?

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- It refers to [protection of clinical trial data](#) required to be submitted to a regulatory agency to prove safety and efficacy of a new drug, and prevention of generic drug manufacturers from relying on this data in their own applications.

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- Represents a [compromise](#) between the innovator drug companies and generic drug companies, where innovator companies get a period of exclusivity.

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- This period allows drug companies to [recoup the investment](#) on clinical trials

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- Once that period is over, a generic company can use the data for its own drug approval.

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- Generic company cannot apply to use the data of the drug in that exclusive period even if the patent is invalidated.

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### How is the data protected?

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- Data exclusivity protects data generated in the course of clinical trials of a drug.

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- Before a drug can be marketed, the [approval regulations](#) require drugs to undergo detailed clinical testing to ensure it is safe to use.

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- The cost of undertaking tests is considerable, involves human subjects and is, therefore, an [arduous exercise](#).

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- Most governments award a drug company that has undertaken clinical trials

with a [period of “exclusivity”](#) which ranges anywhere from five to eight years.

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### **Why there is an issue on this?**

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- Centre considering the proposal to provide a longer period of data exclusivity to ‘new’ drugs from [4 years to 10 years](#).

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- The move comes at the behest of the [United States Trade Representative \(USTR\)](#), which is the arm of the US government tasked with the role of enforcing US intellectual property in markets around the world.

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- Indian Pharmaceutical Alliance is against this as it will impact the [availability of low cost generic medicines](#) in India.

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### **What provisions does Indian Law have?**

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- The Drugs and Cosmetics Act 1940 provides for data exclusivity for a “new drug” under section 122E for a total period of [4 years](#) from the date of approval.

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- A [“new drug”](#) is not defined as a patented drug but simply a drug which has not been used in the country to any significant extent.

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- The regulations require an applicant for a new drug to engage in extensive testing and clinical trials.

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- But, the requirement may be waived for purposes of “public interest” or, if the new drug has been approved and marketed for several years in other countries.

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- Such a requirement is a standard norm to avoid duplication of trials in different jurisdictions which can result in increasing the cost and delaying the introduction of the drug in the market.

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## Why the recent proposal risky?

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- Even when a patent is invalidated, the generic drug company will be prevented from entering the market until the data exclusivity period of 10 years is over.
- The [financial costs](#) prevent the generic companies to conduct their own trials also repeating an exercise is waste of time, resource & energy.
- Increase in the data exclusivity period will affect the [Indian patients](#) detrimentally.

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## Is there any compulsion to increase the data exclusivity period?

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- The WTO TRIPS Agreement under Article 39 [does not subject India](#) or any WTO member to a fixed term of protection and hence it is unnecessary for India to agree to such an increased level of exclusivity commitment.
- Even under the Trans-Pacific Partnership, the proposal for extension of data exclusivity was a subject of severe criticism.

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## Why is US supporting increase of data exclusivity period?

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- US pharmaceutical companies have been trying for years [to slow the introduction of generics](#) by a reversal of section 3(d) of the Indian Patent Act, without much success.
- The UN report on Access to Medication has highlighted the poor quality of high value pharmaceutical patents and raised awareness over the importance of providing access to generic drugs.
- Increasing the period of data exclusivity is the absolute best and [indirect](#)

way of delaying generic competition.

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- Data exclusivity, therefore has become the next big tool for US pharmaceutical industry to indirectly seek market exclusivity.

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### **What should be the way for India?**

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- It is unfortunate that India agreed to extend data exclusivity to 10 years.
- Indian government has to reconsider its position and evaluate where it stands on making drugs affordable for its ever growing population.

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**Source: Business Line**

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