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 investmenton 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.
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- The financial costs prevent the generic companies to conduct their own trials also repeating an exercise is waste of time, resource & energy.
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- 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.
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- 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.
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- 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.
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- 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.
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- 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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