EU’s Suspension of Medicines

Why in news?

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The European drug regulator has recommended suspension of around 300 medicines on which bio-equivalence studies were conducted by the Chennai-based Micro Therapeutic Research Labs (MTRL).

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What the European Medicines Agency says?

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- The European Medicines Agency (EMA) said the suspension has been ordered for all drugs for which the bio-equivalence studies were conducted by MTRL at two sites in India.
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- The review concluded that the data from studies conducted at the [two] sites between June 2012 and June 2016 are **unreliable and cannot be accepted** as a basis for marketing authorisation in the EU.
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- It, however, said there is **no evidence of harm or lack of effectiveness** of medicines authorised and being evaluated in the EU on the basis of the studies at the sites.
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- The regulator also recommended that medicines should not be authorised until bio-equivalence is demonstrated with alternative data.
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What is bio-equivalence study?

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- **Bioequivalence** is a term in pharmacokinetics used to assess the expected biological equivalence of two proprietary preparations of a drug.
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- **If two products are said to be bioequivalent it means that they would be expected to be the same, for all intents and purposes.**
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- Bio-equivalence studies are the **basis for approval of generic medicines.**
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Micro Therapeutic Research Labs (MTRL):

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- MTRL is a contract research organisation which conducts analytical and clinical parts of bio-equivalence studies, some of which are used to support marketing authorisation applications of medicines in the EU.
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\n**Source: The Hindu**

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