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Clinical trials may get nod to check injectable contraceptives' efficacy?

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Failure of its various family planning acceptors such as condom and contraceptive pills to check population boom has prompted the Union Health Ministry to re-examine option of granting permission to the ICMR to conduct clinical trials for the efficacy of the injectable contraceptives like Cycloferm.

Presently, such injectable contraceptives are in the list of banned drugs under section 26 A of the Drugs and Cosmetic Act because of its alleged adverse side-effects though the contraceptives are already available in the private sector.

Sources in the Union Health Ministry said that recently its highest authority on technical matters, Drugs Technical Advisory Board (DTAB), has decided to set up an expert committee to examine the overall safety and efficacy profile of the drug if it could be allowed for clinical trial by the ICMR.

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The panel will be consisting of gynaecologists and pharmacologists to examine the overall safety and efficacy profile of the drug including assessment of the bone mineral density, if any done by the ICMR during the clinical trial.

If all goes well, the ICMR's application to DCGI seeking conducting a study on *Pre-programme introduction of injectable contraceptive Cycloferm and Net-EN through district hospitals and NGO clinics* — An ICMR Task Force Study might be given go ahead.

To make this happen, the DCGI has to lift the ban it had imposed way back in 1983 on the fixed dose combinations of injectable preparations containing synthetic oestrogen and progesterone following allegations that the drugs are prone to cause reduction in bone mineral density.

"However, this would depend on the report of the expert committee which will be soon set up," said a senior official from the DCGI.

He said that the injectable preparation containing Medroxy progesterone acetate and estradiol cypionate (Cycloferm) are available in USA, Indonesia, Hong Kong and Thailand. The preparation is also included in the WHO model list of Essential Medicines, the official added.

The move is also being seen as a government attempt to provide wider range of contraceptives to the families whose demand remains unmet. Moreover, the injectable contraceptives are already available in the private sector.

Clinical Research.

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