



A New Vaccine

What is the issue?

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A new vaccine manufactured by Pune-based Serum Institute of India has shown 66.7% efficacy against severe rotavirus gastroenteritis among infants in Niger in West Africa.

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What is special about Serum Institute's new rotavirus vaccine?

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- Serum Institute of India is the world's largest vaccine maker, producing and selling more than 1.3 billion doses globally every year.

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- **Rotavac, a rotavirus vaccine produced by Hyderabad-based Bharat Biotech, became part of India's Universal Immunisation Programme (UIP)** when it was introduced in 4 states in April 2016, and was subsequently extended to 5 more states last month.

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- The key step forward in the manufacture of Serum Institute of India's new BRV-PV vaccine — to be ultimately called **Rotasiil** — is that it does not, unlike Rotavac, require refrigeration, and is, therefore, easier to store in low-income countries where rotavirus poses the greatest threat to children.

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- BRV-PV has completed Phase III trials in Niger, and shown good efficacy in heat-challenge conditions.

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- **This trial brings a vaccine which is adapted to African settings to those who need it most.**

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- The Institute had decided to develop a **heat-stable vaccine** to overcome the absence of cold chains in many poor countries.

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What challenges does the global immunisation programme face?

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- **According to the World Health Organisation, vaccines prevent an estimated 2 million to 3 million deaths every year**, but an additional 1.5 million deaths could be prevented if the global immunisation cover improved.
- In 2015, an estimated 19.4 million infants worldwide did not receive routine immunisation.
- A special supplement to Vaccine, a peer reviewed medical journal, noted with concern that outdated vaccine supply and distribution systems were delaying and limiting the impact that vaccines have in safeguarding people's health.
- According to one study in the Vaccine collection, every year, 1 in 3 countries worldwide experiences a stockout of at least 1 vaccine for a minimum of 1 month, and the problem is most pronounced in sub-Saharan Africa.
- Many vaccines can lose potency if exposed for too long to temperatures outside the recommended range of 2 degrees to 8 degrees Celsius.
- The vaccine 'cold chain' strives to maintain proper temperatures for vaccines from manufacturing facilities to storage facilities, health centres, and immunisation clinics.
- Each year, rotavirus gastroenteritis is responsible for about 37% of deaths from diarrhoea among children younger than 5 years of age worldwide, with sub-Saharan Africa bearing a disproportionate burden. The BRV-PV vaccine has the potential to reduce this burden.

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When will the vaccine be sold in India, and at what cost?

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- The vaccine is already licensed in India, and is under the WHO pre-qualification process.

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- Once approved, low-income countries will be able to procure the vaccine at an affordable price and make it available to their populations.
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- Serum Institute plans to produce around 60 million doses to begin with, and hopes to roll out the vaccine in August- September this year.
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- The cost is likely to be under \$ 2 — between Rs 100 and Rs 120 — per dose.
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Source: Business Standard

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