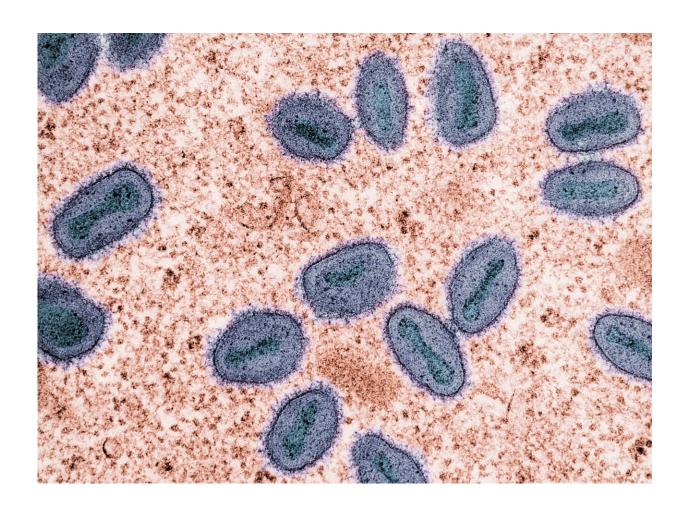


Mpox vaccine maker seeks approval for use in teens

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Danish drugmaker Bavarian Nordic said Friday it was seeking European approval to use its mpox vaccine in children aged 12 to 17, after the



WHO declared the current virus surge a global public health emergency.

The World Health Organization (WHO) this week declared the rapid spread of the new, more dangerous mpox strain, dubbed Clade 1b, a public health emergency of international concern—the highest alarm the UN agency can sound.

Bavarian Nordic's vaccine is currently only approved for people 18 years and older.

"Children and adolescents are disproportionately affected by mpox in the ongoing outbreak in Africa, highlighting the importance and urgency to broaden the access to vaccines and therapies for this vulnerable population," Bavarian Nordic chief executive Paul Chaplin said in a statement.

The company said it had presented the European Medicines Agency with <u>clinical data</u> from a study which showed "non-inferiority of immune responses from mpox/<u>smallpox vaccination</u> in adolescents and (a) similar safety profile compared to adults."

The US Food and Drug Administration (FDA) granted the vaccine an "emergency use authorization" for adolescents during the 2022 global mpox outbreak.

The <u>virus</u> has swept through the Democratic Republic of Congo, killing 548 people so far this year.

Sweden and Pakistan have this week reported the first cases of the virus outside of Africa, with the WHO warning further imported cases of the new strain in Europe were likely.

The infectious disease is caused by a virus transmitted to humans by



animals but can also spread human-to-human through close physical contact.

It causes fever, muscular aches and large boil-like skin lesions.

On Thursday, Bavarian Nordic said it was ready to produce 10 million vaccine doses by 2025 but was waiting for countries to place orders.

It said it has some 500,000 doses in stock.

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