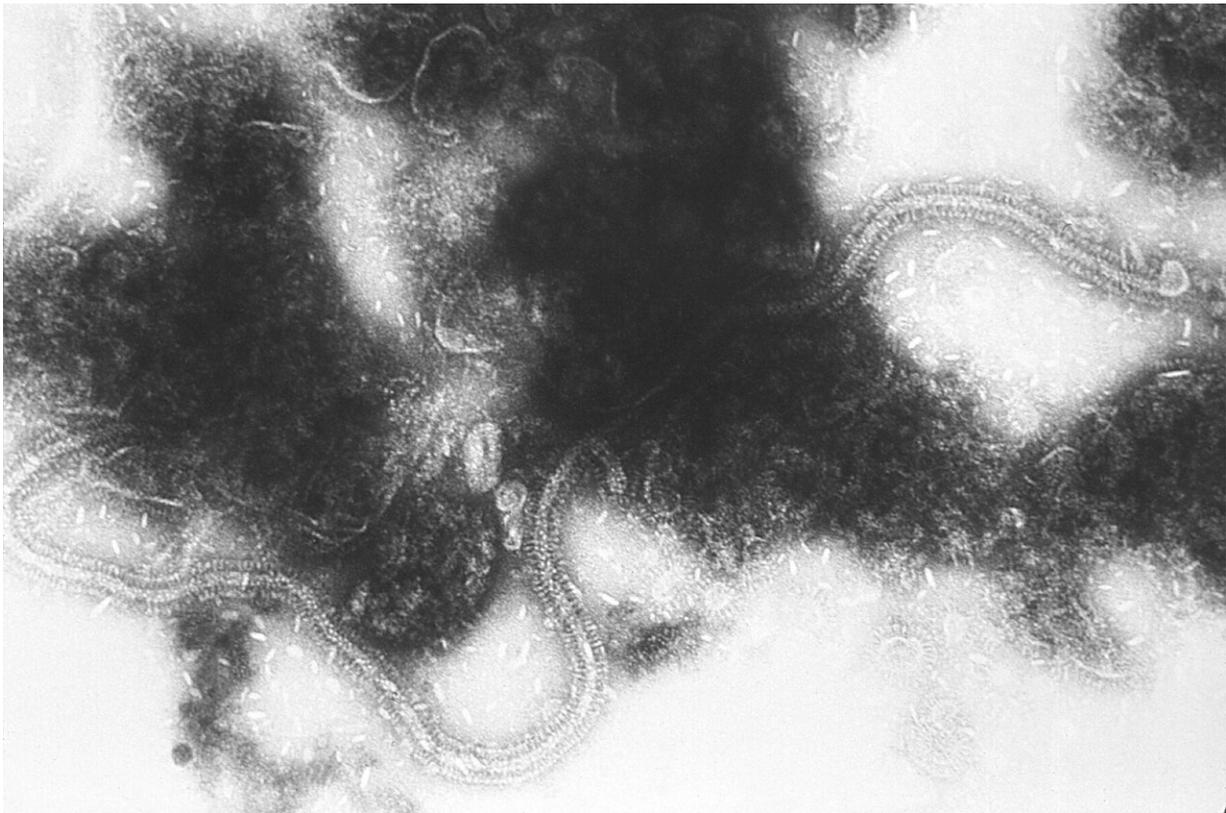


# EU drug watchdog approves first RSV infant, elderly vaccine

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Transmission electron micrograph of RSV. Credit: CDC/ Dr. Erskine Palmer / Public Domain

Europe's drug watchdog on Friday approved the world's first vaccine for infants and those over 60 against the Respiratory Syncytial Virus, a

major cause of hospitalization on the continent, the Amsterdam-based agency said.

RSV normally causes mild, cold-like symptoms, but can be serious for infants, the elderly, those with weak immune systems and underlying conditions.

It is a leading cause of pediatric hospitalization in Europe, the EMA said.

In severe cases it can cause pneumonia and bronchiolitis, an inflammation of the small airways deep inside the lungs.

The medicine, called Abrysvo and made by Pfizer, was approved in the United States in May.

It followed the EU-wide approval of GlaxoSmithKline's anti-RSV drug called Arexvy last month, which like Pfizer's shot could also be used for people over 60.

British-Swedish pharmaceutical firm AstraZeneca and France's Sanofi's say their drug nirsevimab, marketed as Beyfortus, was the first treatment to prevent severe illness from RSV in infants—and was approved in the EU in November last year.

"Abrysvo is the first RSV vaccine indicated for passive immunization of infants from birth through six months of age following administration of the vaccine to the mother during pregnancy," the EMA said.

"This vaccine is also indicated for active immunization of adults aged 60 years and older," it added.

The approval of the new RSV vaccines is the culmination of a decades-

long hunt to protect vulnerable people from the common illness.

Abrysvo is a bivalent vaccine—meaning it protects against more than one virus strain—and when given to a person, their immune system generates specific antibodies and T-cells (immune system cells) that help prevent RSV infection.

"In case of pregnant individuals, the neutralizing antibodies cross the placenta, providing infants with protection up to six months after birth," the EMA said.

"Today's... positive opinion represents a significant step forward in our efforts to help prevent RSV disease in older adults and infants," Pfizer senior vice president and vaccines chief Annaliesa Anderson said.

"If approved, our RSV vaccine candidate for pregnant individuals would help protect infants immediately at time of birth through six months of age, when they are at highest risk of severe RSV disease and complications," she said in a statement.

"This, along with an approval for older adults, would mark meaningful public health progress for RSV disease prevention throughout Europe," Anderson said.

Analysts predict the market could be worth more than \$10 billion in the next decade, with similar shots from other makers including Moderna expected to follow soon.

The EMA's finding will now be sent to the European Commission for a final decision for EU-wide marketing authorization.

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