

EN  
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Answer given by Ms Kyriakides  
on behalf of the European Commission  
(19.2.2020)

Novartis' Zolgensma has received a marketing authorisation in the United States, but the product has not yet been authorised in the EU. The marketing policies and possible price for the product, which the company would apply in the EU, have therefore not been communicated.

A "lottery", making the medicine available free of charge to a limited number of children, is not a viable model. The health of patients cannot become dependent on a game of chance. Instead, it is for companies to develop a sustainable model that meets societal needs.

The Commission is committed to improving the supply of affordable medicines to meet Europe's needs and at the same time maintaining the status of a world leader in innovation for the European pharmaceutical industry. To pursue and achieve these objectives, the Commission will launch a Pharmaceutical Strategy for Europe.

It may be noted that EU Member States' patent laws do include compulsory licensing provisions.

Measures regulating the prices and reimbursement of medicines within the EU are a national competence<sup>1</sup>. The Commission, however, is committed to support Member States in constantly improving the quality and sustainability of their health systems<sup>2</sup> and address the challenges linked to affordable medicines. The 2019 EU State of Health report<sup>3</sup> highlights ways that EU can help decisions at national and local level, such as sharing experiences on pricing and payment methods at EU level.

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<sup>1</sup> Articles 34, 36 and 168(7) Treaty on the Functioning of the EU: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:12012E/TXT&from=EN>

<sup>2</sup> [https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-stella-kyriakides\\_en.pdf](https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-stella-kyriakides_en.pdf)

<sup>3</sup> [https://ec.europa.eu/commission/presscorner/detail/en/IP\\_19\\_6336](https://ec.europa.eu/commission/presscorner/detail/en/IP_19_6336)