Human medicines: highlights of 2018

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EMA has published an overview of its [key recommendations of 2018](https://www.ema.europa.eu/documents/report/human-medicines-highlights-2018_en.pdf)  on the authorisation and safety monitoring of medicines for human use.

New medicines are essential for public health as they can improve the treatment of diseases. In 2018, EMA recommended 84 medicines for [marketing authorisation](https://www.ema.europa.eu/en/glossary/marketing-authorisation). Of these, 42 had a new [active substance](https://www.ema.europa.eu/en/glossary/active-substance) which has never been authorised in the EU before. Many of these medicines represent a significant improvement in their therapeutic areas; they include medicines for children, for rare diseases and advanced therapies.

Once a medicine is placed on the market, EMA and the EU Member States continuously monitor the quality and the benefit/risk balance of the medicine under its authorised conditions of use. In 2018, EMA gave new safety advice to manage risks observed with a number of medicines on the market in the EU. Regulatory measures ranged from a change to the [product information](https://www.ema.europa.eu/en/glossary/product-information) to the suspension or withdrawal of a medicine. An overview of some of the most notable recommendations is also included in the document.