How are new medicines approved by EMA?

15/08/2018

How are new medicines approved by EMA?

Find out what it takes to develop a medicine and to get it authorised

All medicines must be authorised before they can be marketed and made available to patients in the European Union (EU).

When all the relevant information has been collected from laboratory tests and clinical trials, the European Medicine's Agency's (EMA) scientific committees conduct a comprehensive scientific evaluation of the data and provide independent recommendations on medicines for human and veterinary use.

If the benefits of the medicine are greater than its risks, EMA gives the green light and recommends to the European Commission that the medicine can be marketed across the EU, as well as in the European Economic Area.

Once the medicine is on the market, the Agency continues to monitor its safety.

For an easy introduction to the evaluation and approval of medicines, watch this video.

[embedded content]

For further information, see our webpage on the authorisation of medicines in the EU.