

KEEPING MEDICINES SAFE

What actions can EMA take?





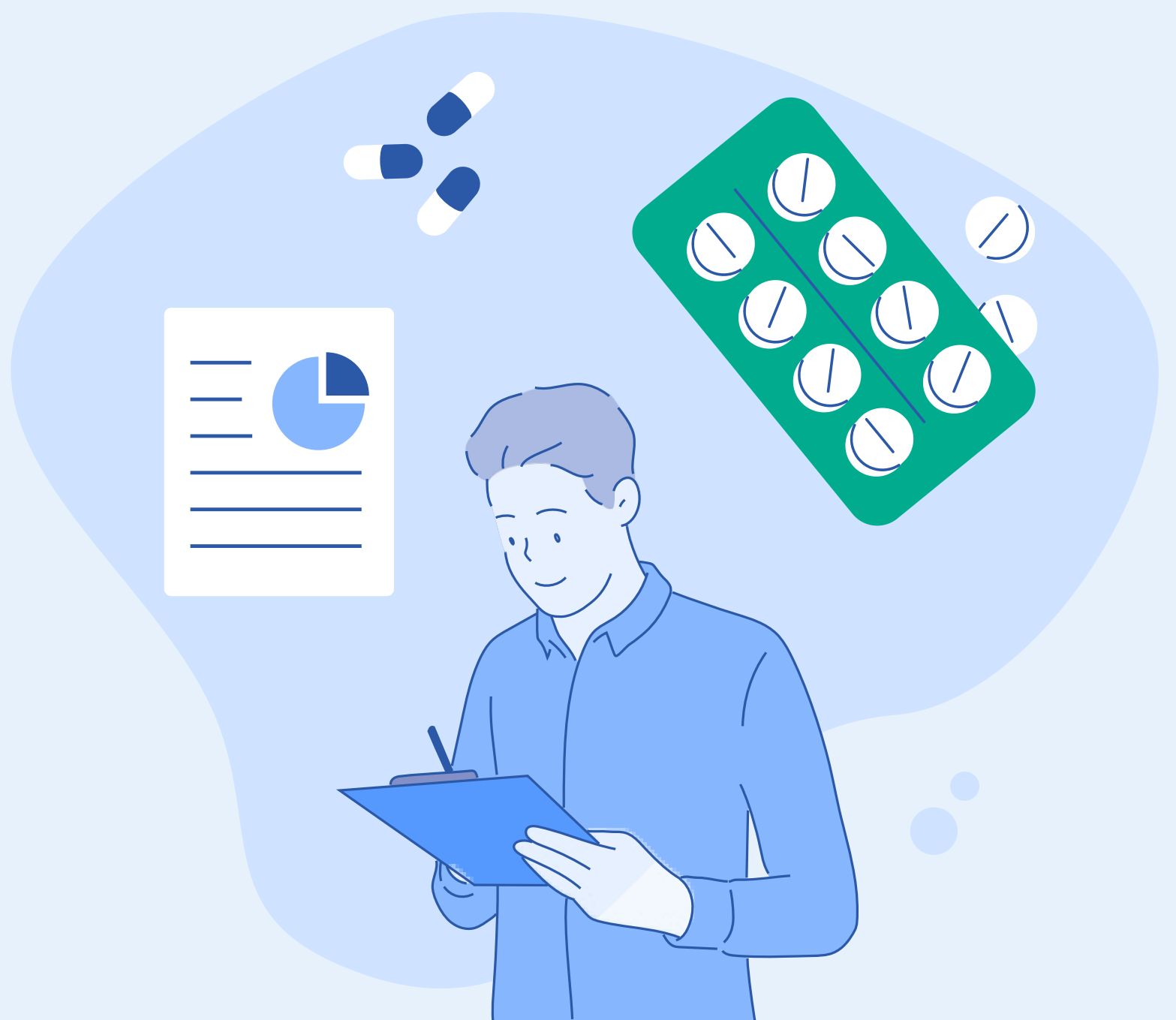
Monitoring and assessment

If a new safety concern arises with a medicine, we run an assessment to determine the most appropriate response.

Updating information or requesting new data

Following the assessment we can:

- Require the company to conduct additional studies
- Add new side effects or warnings to the summary of product characteristics (SmPC) and the package leaflet



Restricting, suspending or withdrawing

If stronger measures are needed, we may:

- Change how a medicine is used or introduce restrictions
- Temporarily suspend its marketing authorisation while more data are collected
- Cancel its marketing authorisation if the risks outweigh the benefits



A continuous commitment to safety

Through these measures, EMA and national authorities work together to make medicines safer for everyone in the EU.

