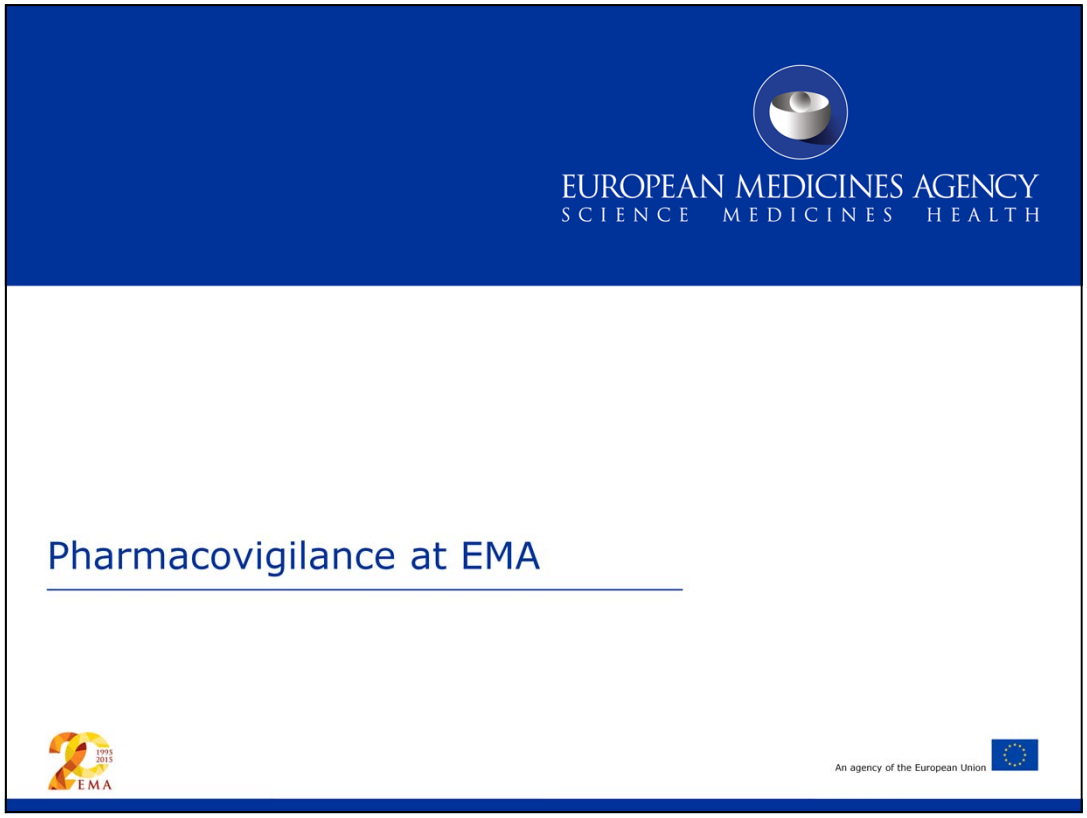
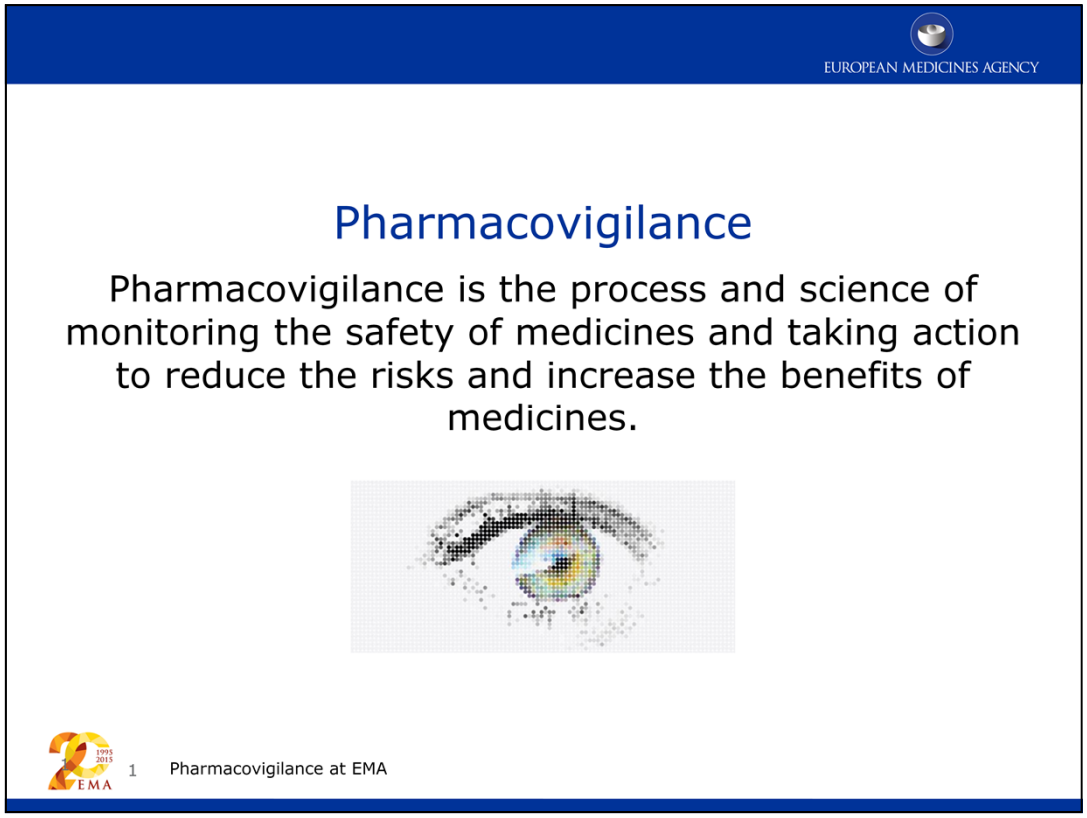


In this video you will hear about pharmacovigilance, what it means and the role of the European Medicines Agency



But first let's define what pharmacovigilance is …

Pharmacovigilance is about monitoring the safety of medicines.

The term pharmacovigilance relates to both the *science* and the *actions* taken to ensure that medicines are safe.

To reduce their risks and increase their benefits.

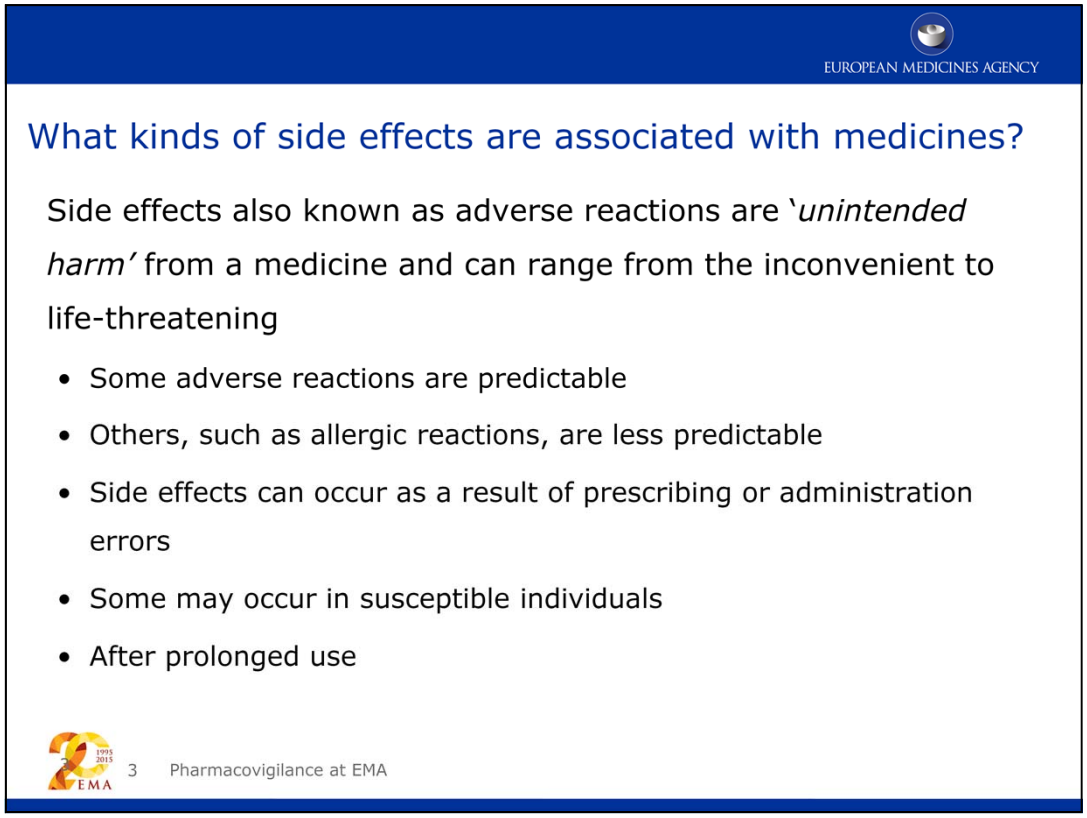
In the next few minutes you will learn more details on pharmacovigilance.

Why do we need Pharmacovigilance? Firstly, we are always learning more about medicines.

Medicines are tested extensively in clinical trials before they are authorised and at this time their safety is evaluated.

However more can be learnt once the medicines are in use.

Pharmacovigilance is therefore vital, it means that the safety of all medicines is monitored throughout their use and information on risks is generated and appropriate action can be taken.

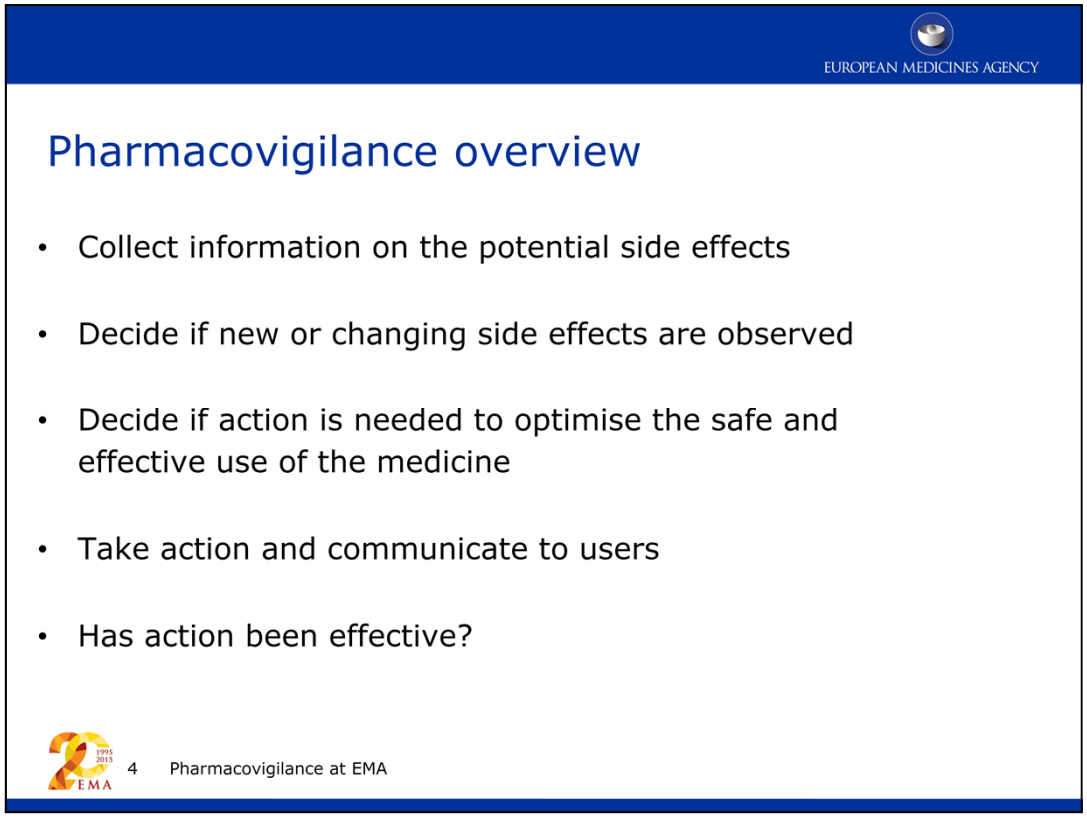


As we have said not everything can be known about the side effects of a medicine until it has been used by many people over time.

Side effects (also known as adverse reactions) can range from the inconvenient to life threatening effects

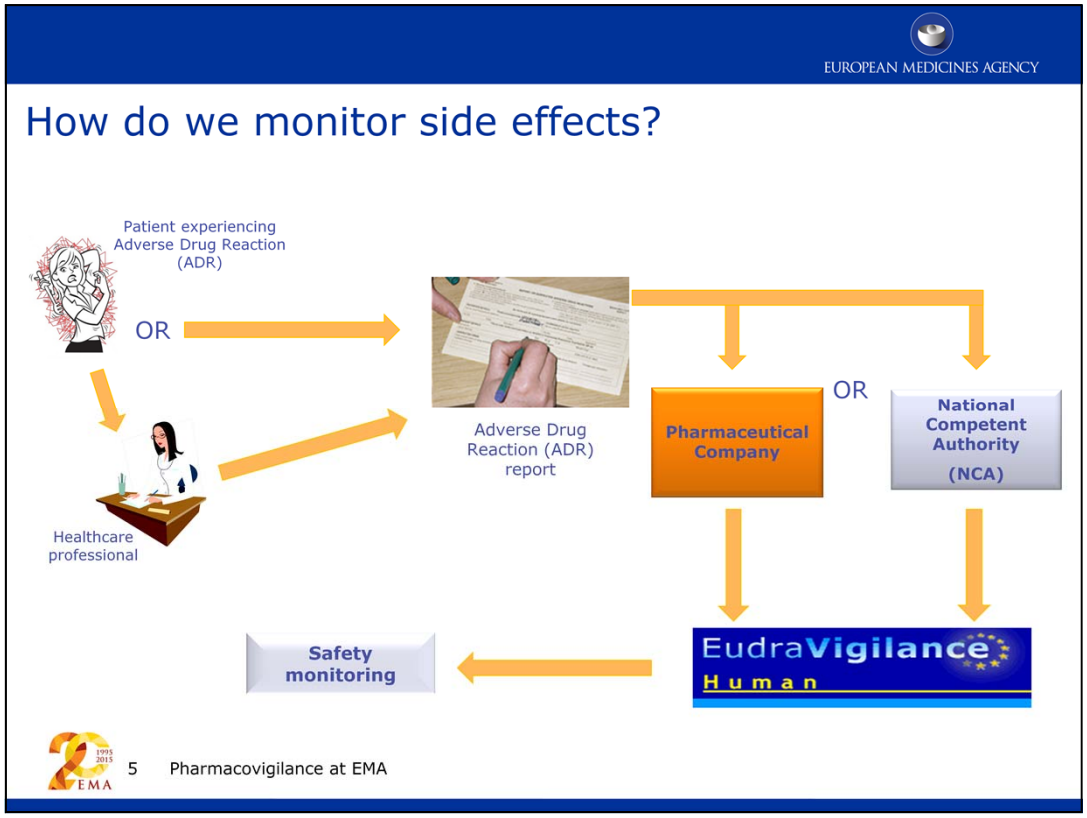
In some cases it is possible to foresee potential side effect while others are less predictable.

Some side effects can be caused as a result of prescribing or administration errors while others are due to susceptibility of specific individuals or only occur after prolonged use.



The process of pharmacovigilance involves several distinct steps such as collection of information on potential side effects, detecting if any new or changing side effects have arisen, deciding if action is needed to optimise the safe and effective use of the medicine and then communicating this to the users of the medicine.

It is also important to follow up as to whether the actions taken have been effective…

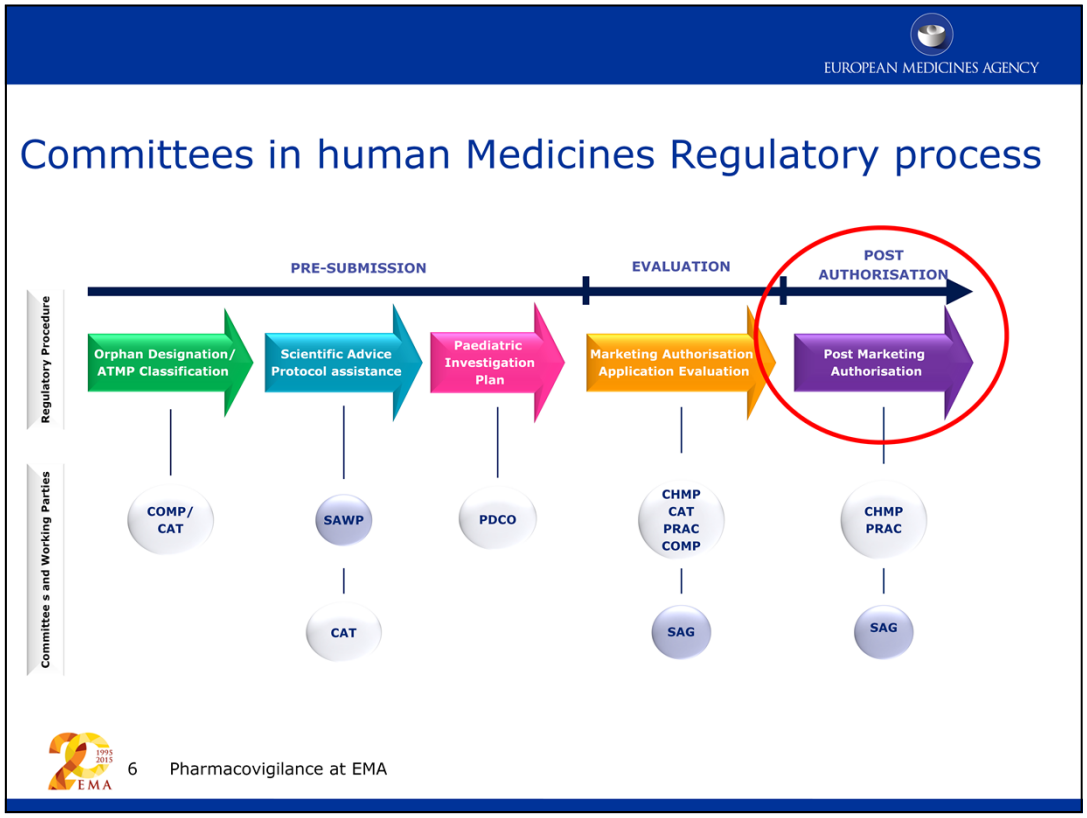


Both medicines regulators and the pharmaceutical companies monitor the safety of medicines for as long as they are on the market and if necessary, will take actions to protect patients in the EU.

When adverse reactions or side effects occur, an individual can either report this directly or can inform their healthcare professional. An *Adverse Drug Reaction* report is completed and is then sent to the pharmaceutical company or to the National Competent Authority who then transmit this information to Eudravigilance

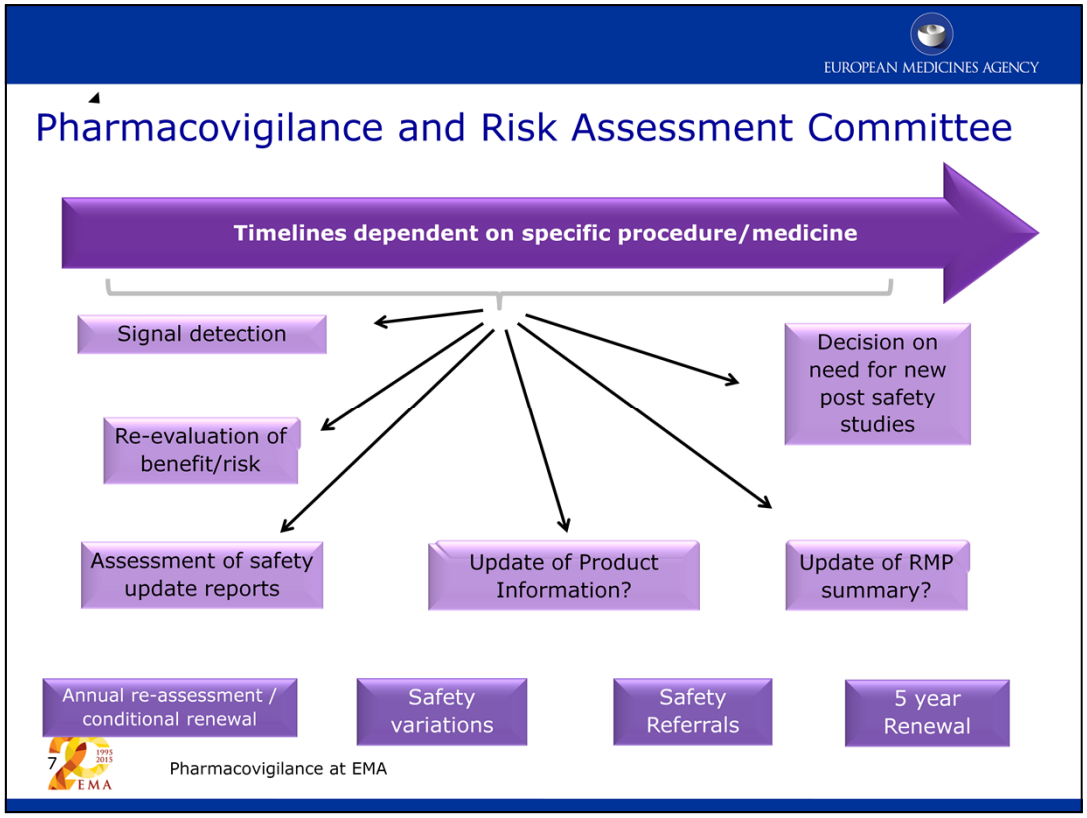
Eudravigilance is a database, which is the central repository for reports, data-storage and data analysis of side-effect reports in the EU and the European Medicines Agency is responsible for maintaining this database.

Reports are constantly monitored for any signals that indicate unexpected reactions to particular medicines.



To put these activities in perspective, **this** is the point in the process that we are particularly focusing on here.. ….Post-authorisation

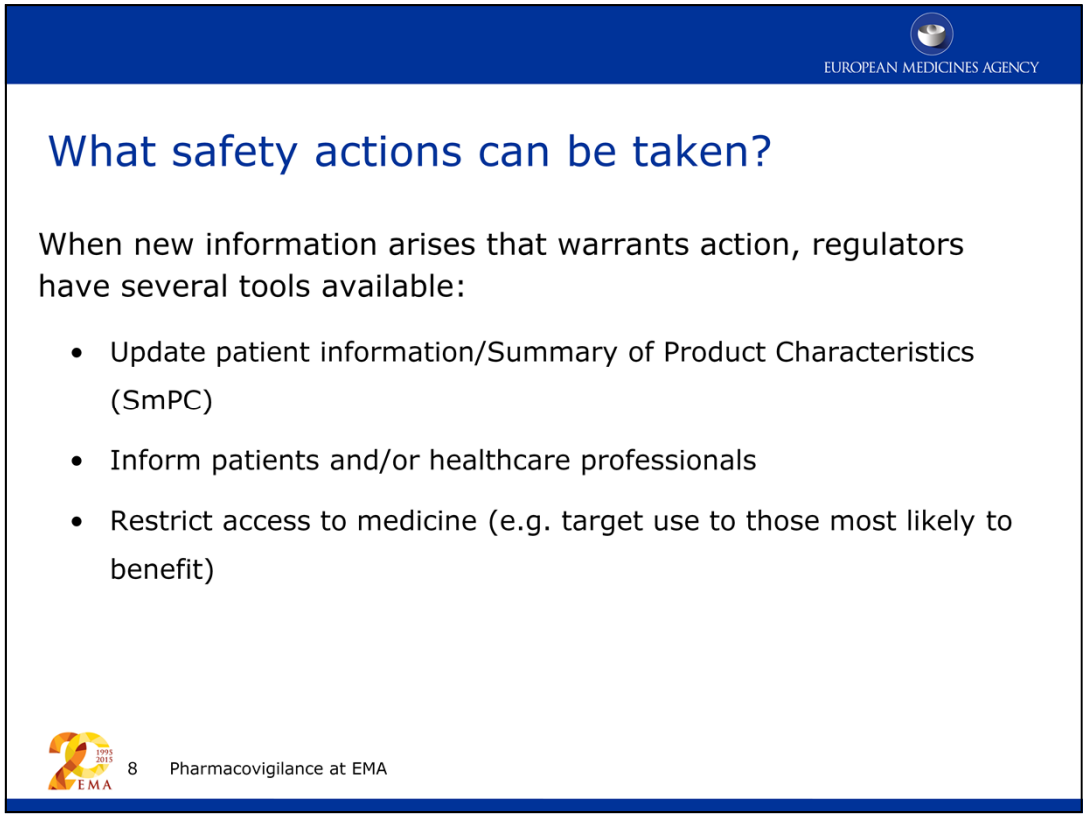
The Pharmacovigilance Risk Assessment Committee (PRAC) is the committee that carries out most of the EMA's work on pharmacovigilance.



The mandate of the PRAC covers all aspects of the risk management of medicines and you can see a few of their activities here

The main responsibility of the PRAC is to prepare recommendations on any questions on pharmacovigilance activities related to a medicine including risk-management and the effectiveness of risk reduction activities taken.

The PRAC generally provides these recommendations to the EMA Committee for Medicinal Products for Human Use and the European Commission.



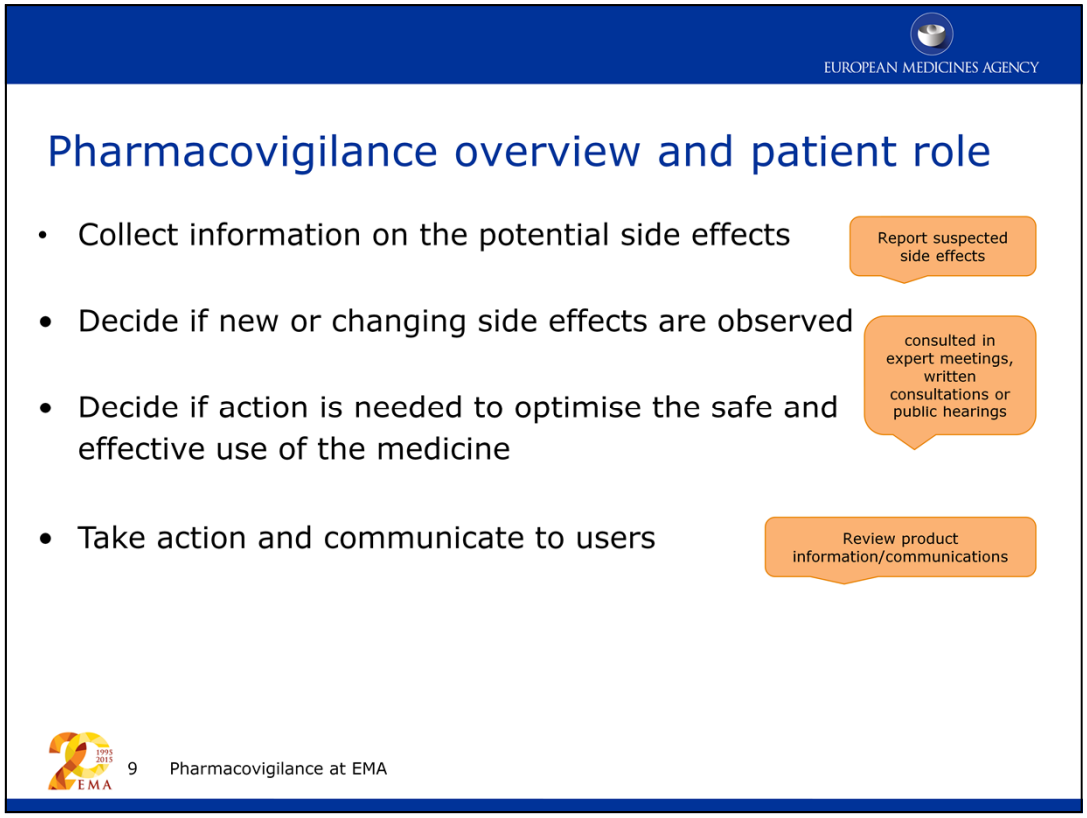
Once the PRAC has been informed of a safety issue, what actions can be taken?

Patient information can be updated as well as the Summary of Product Characteristics for the healthcare professionals

Patients and Healthcare Professionals can also be informed via safety communications including direct healthcare professional communications and educational material

The Benefit-Risk profile can be reviewed via a referral

And in some cases, access to the medicine can be restricted



Coming back to this overview, we see the role that patients and healthcare professionals can play–

They are involved throughout from **reporting** adverse events (as already described) to being involved in pharmacovigilance decisions through their membership on the PRAC committee

Patients and healthcare professionals participate as experts in specialist meetings such as Scientific Advisory or Ad-Hoc expert groups or can contribute via written consultations on risk minimisation actions..

And will be involved in the public hearings that will be convened around particular issues

Finally, they review product information and safety announcements

If you would like to learn more about any of these activities….

please use our Frequently Asked Questions section or visit the Pharmacovigilance section of our website: www.ema.europa.eu