In this video, we will briefly describe the process of monitoring the safety of medicines in the EU and how patients and the public can be involved.

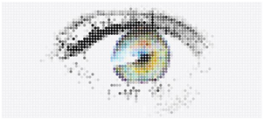
EUROPEAN MEDICINES AGENCY

Why do we need pharmacovigilance?

The use of medicines involves a trade off between benefits and risks (the potential for harm).

Pharmacovigilance:

- is the monitoring of the safety and efficacy of medicines
- relates to every aspect of the life cycle of a medicine and includes:
  - Quality of manufacture of a medicine
  - Adverse drug reactions
  - Errors in prescribing and administration



Eudravigilance – pharmacovigilance database

What is a Safety Referral

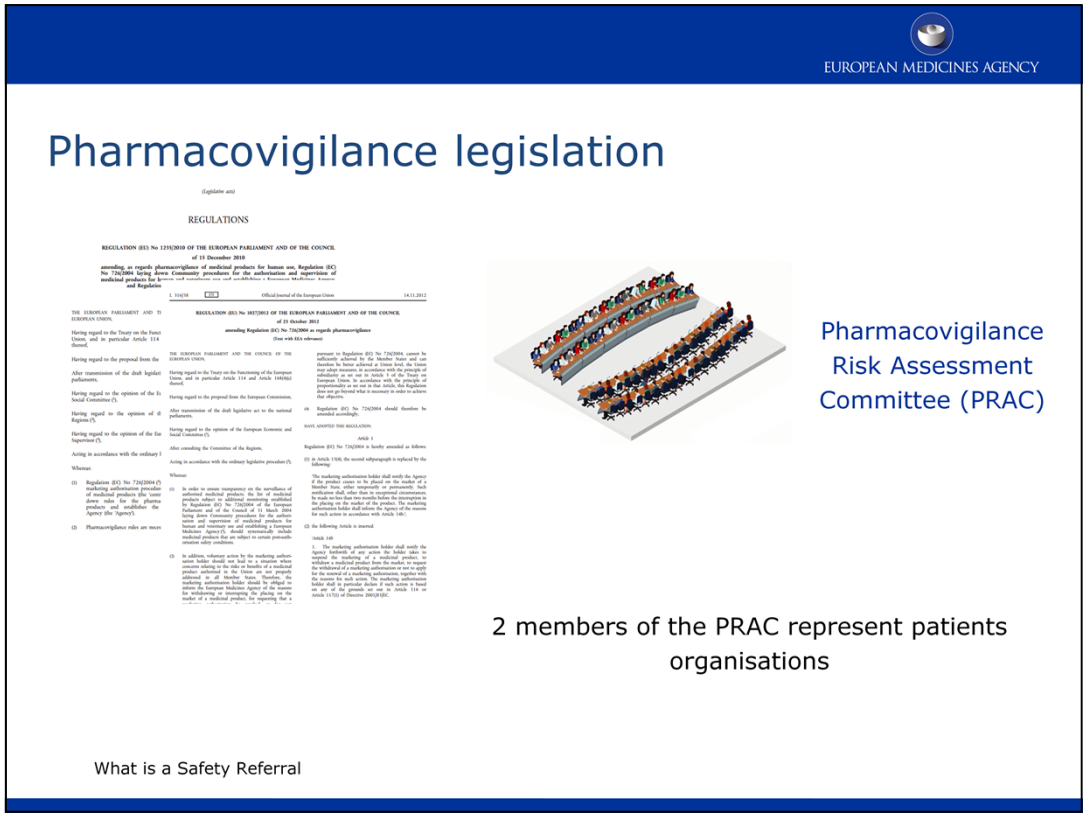
There is a risk associated with taking any medicine.

Before a medicine can be marketed, the benefits and risks are evaluated and the medicine is only authorised if the benefits outweigh the risks.

The safety and effectiveness of medicines is monitored at every point during the lifecycle of a medicine; from the quality of its manufacture to any reactions that occur during its use as well as any errors in dosing or incorrect use.

This process of safety monitoring is called ***Pharmacovigilance***. Safety monitoring is shared between the EU member states and EMA, which also coordinates the process.

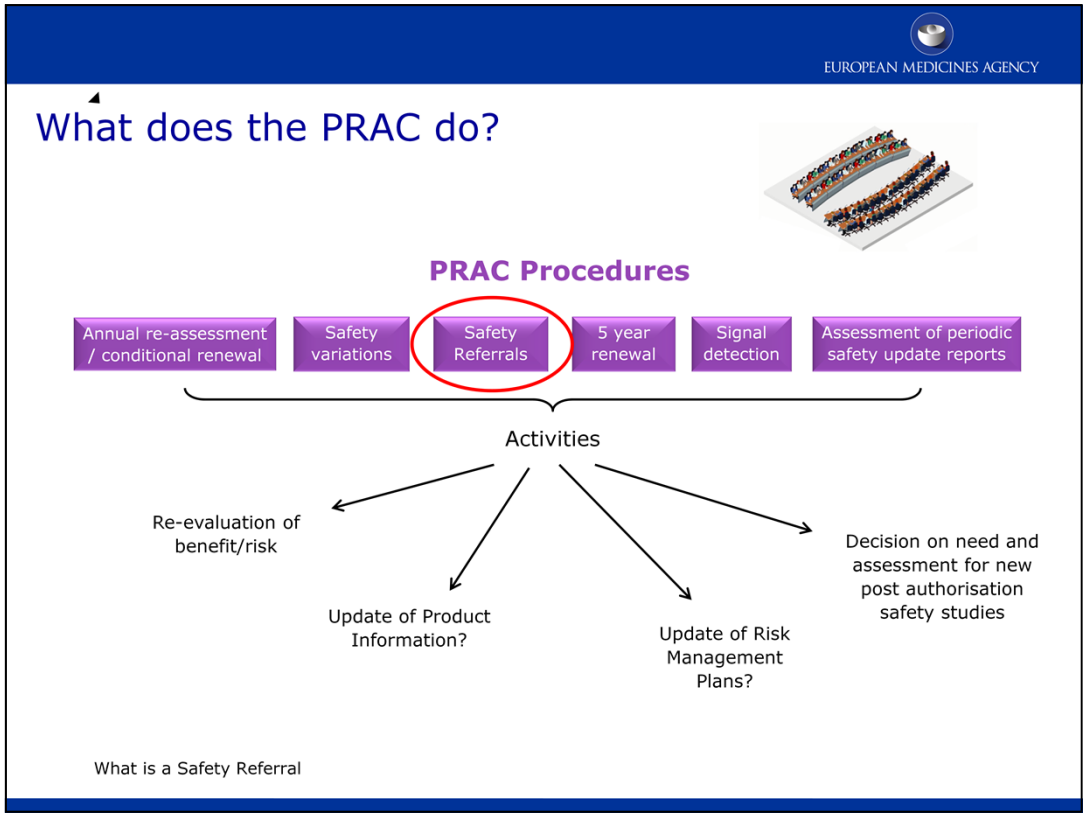
Data from various pharmacovigilance activities is collected in a database called Eudravigilance and evaluated as a matter of routine.



New European pharmacovigilance legislation came into operation in July 2012.

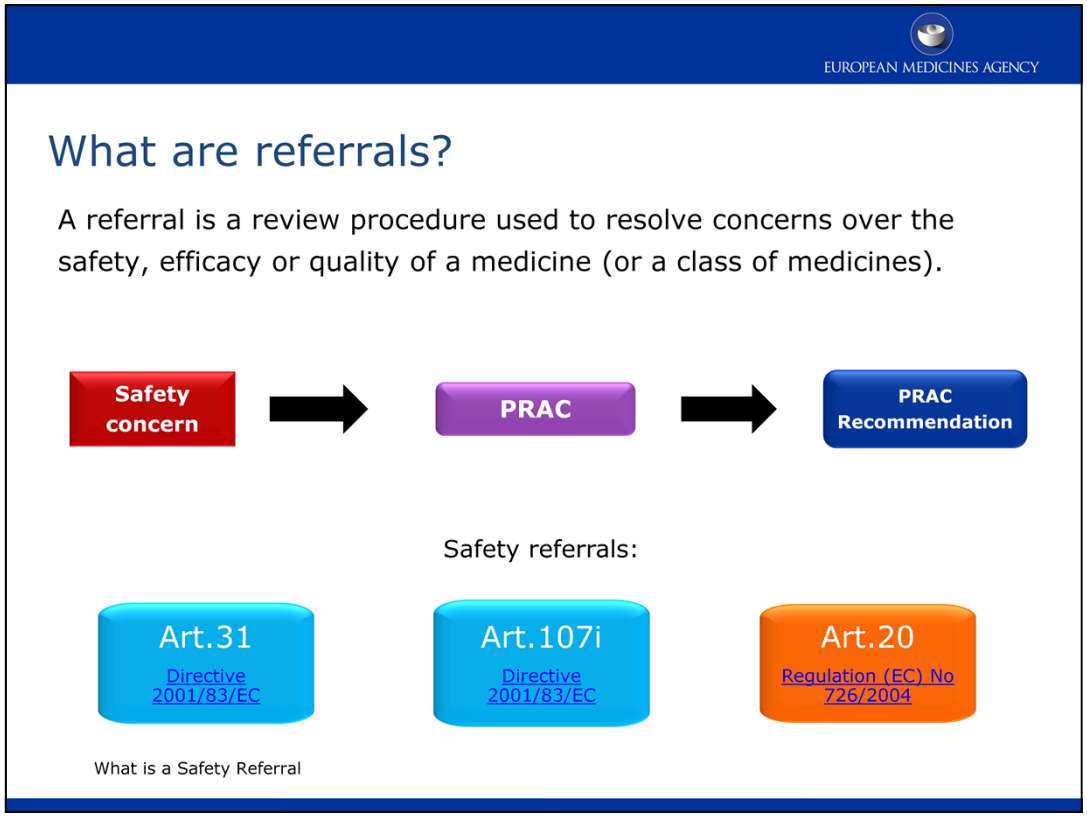
The purpose of this legislation is to *promote and protect public health* by strengthening the existing Europe-wide system for monitoring the safety and benefit-risk balance of medicines

Included in this legislation was the provision to formally establish the Pharmacovigilance Risk Assessment Committee (or PRAC), which is composed of experts from each of the member states of the EU and European Economic Area (EEA) as well as two members representing patients organisations.



The PRAC is responsible for all aspects of risk management of medicines ranging from the detection and assessment of safety issues to their minimisation, and communication of the risks of a medicine and measures to prevent them.

One important aspect of the PRACs work is safety referrals…



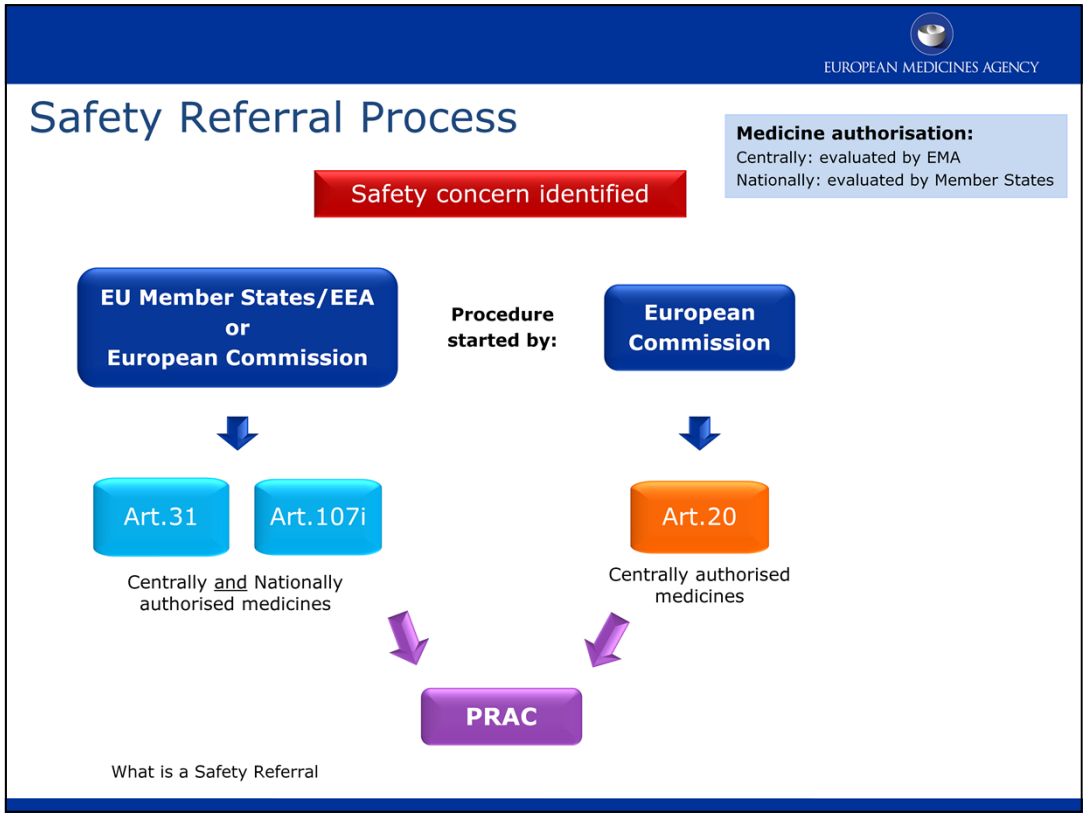
A referral is a review procedure used to resolve issues such as concerns over the safety, efficacy or quality of a medicine (or class of medicines) on behalf of the European Union and the European Economic Area (EEA).

Safety referrals involve a review of the safety concern by the PRAC, who then come up with a recommendation.

Several different types of referrals exist and we refer to them by the specific articles of the legislation in which they are defined.

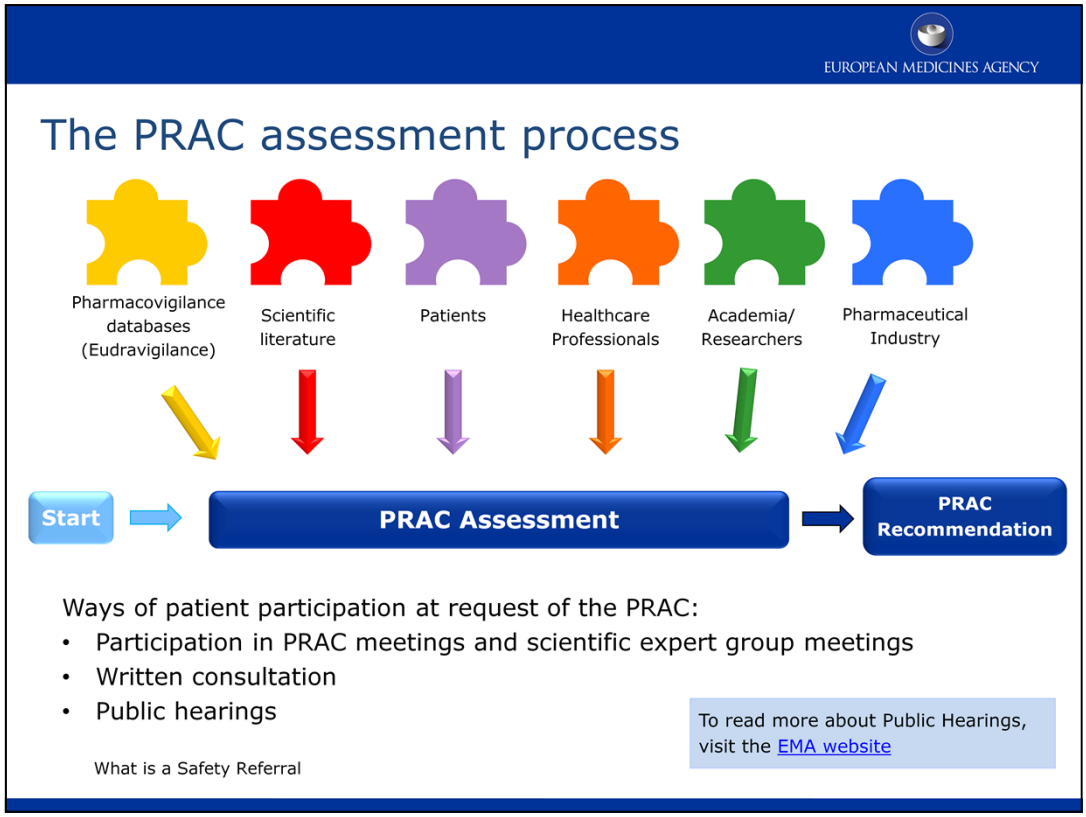
This video will focus on the three types of safety referrals - Article 31, Article 107i and Article 20 - which are assessed by the PRAC.

Question and answer documents providing more details can be found by clicking on the links in the pdf version of this video.



Let's go through the process..

- The safety of medicines throughout the EU is under constant review.
- If a safety concern is identified that cannot be managed by routine measures, a referral procedure can be started– either by a national medicines agency in the Member States or by the European Commission
- A notice is circulated to the EMA, the PRAC, all Member States and the European Commission informing them of the safety issue.
- The referral procedure that is used depends on the nature of the concern and on whether the medicine or medicines in question have been authorised centrally (that is via the EMA) or by national medicines agencies.
- Articles 31 and 107i are referral procedures used when the issue affects nationally authorised medicines or both nationally and centrally authorised medicines; the difference between these procedures is the urgency of the situation and how much time is allowed for the referral procedure;
- Whereas Article 20 referral procedures are used for issues that only centrally authorised medicines.
- The issue is then assessed by the PRAC

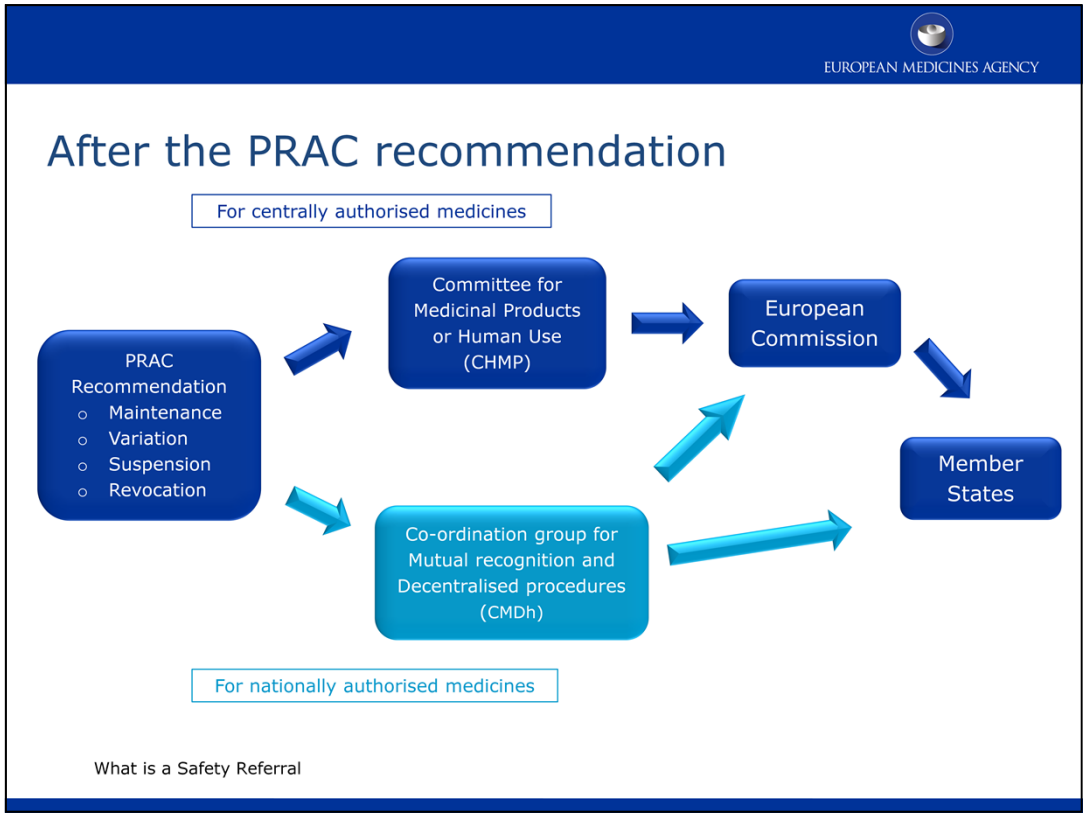


The PRAC will assess all available data including data collected via Eudravigilance and in published scientific literature.

The PRAC may also consult patients, healthcare professionals and academia as well as the pharmaceutical company (or companies) that hold the marketing authorisation for the medicines in question.

All of these inputs are considered during the PRAC assessment and reflected in the recommendation reached. The outcome is described in an Assessment Report that is published on the EMA website.

Patient contributions can be made in person during the PRAC monthly meetings or at specially convened scientific expert group meetings. Patients can contribute in writing or in the context of a Public Hearing.



The PRAC may recommend to:

- Maintain the current marketing authorisation
- Vary the authorisation – that is to change the way a medicine is used or to impose certain conditions on its use
- To suspend (that is to stop the use of the medicine) or
- Revoke the marketing authorisation of the medicine (or class of medicines) – that is to take it off the market permanently

The PRAC recommendation is forwarded for consideration to one of two committees, who will issue what is called 'a final position'.

For procedures involving at least one *centrally* authorised medicines, the PRAC recommendation is sent to the CHMP (the Committee for Medicinal Products for Human Use). The CHMP position is then sent to the European Commission, who adopt a legally binding decision, which is sent to the Marketing authorisation holders and the Member States.

For procedures involving only *nationally* authorised medicines, the recommendation is sent to a group called the CMDh (Co-ordination group for Mutual recognition and Decentralised procedures – the h is for human medicines).

CMDh represents the Member States, so if it agrees by consensus on the recommendation, its position can be put into practice directly by each country. If only a majority of CMDh members agree, then the position is sent to the European Commission to provide a unified legal decision in the same way as previously described.

The EMA webpage for the specific procedure is updated with the position and all its annexes; in all EU languages.

If you would like to read more about referral procedures and public hearings, please visit our website at www.ema.europa.eu