



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## How the European Medicines Agency interacts with patients and consumers

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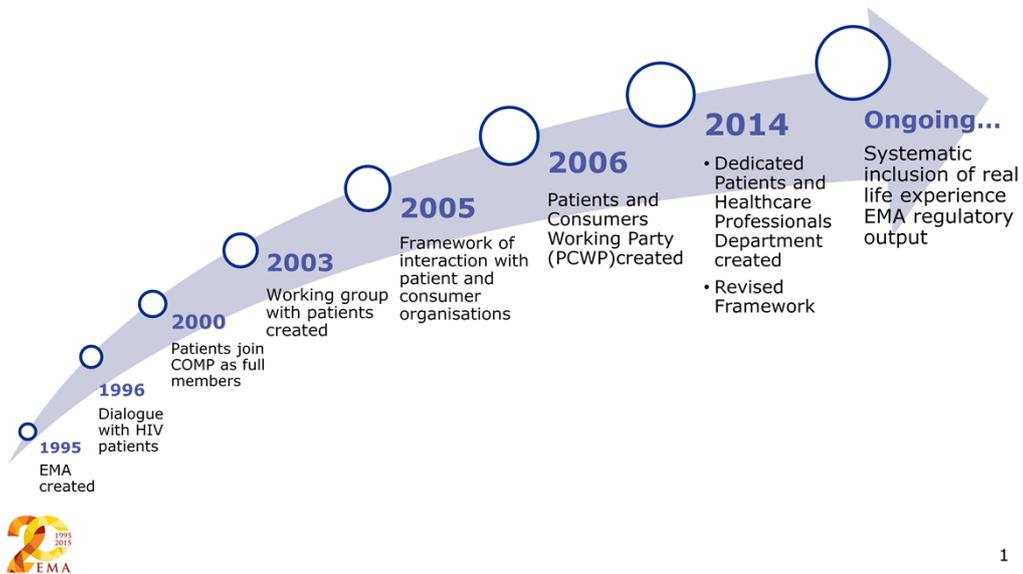


An agency of the European Union



In this video we are going to tell you how the EMA works with patients, carers and consumers

## Interaction with patients: the EMA journey... so far



The EMA's interactions with patients has been a long collaborative journey – starting when the Agency opened back in 1995

In 2000, patients became members of a scientific committee for the first time – the Orphan committee

A working group with patients was formed in 2003 followed by the formal adoption of a Framework of Interaction with patient organisations in 2005. In 2006 was the creation of the Patients' and Consumers' Working Party ...

After 20 years of collaboration, the EMA now has in place, systems to involve patients along the entire lifecycle of its medicines evaluation process.

We are strongly committed to ensure that this continues to grow and evolve.

## How are patients involved at EMA?



So how are patients involved at EMA?

We mentioned earlier that they are involved along the whole medicines lifecycle and there are different ways that they can be involved...

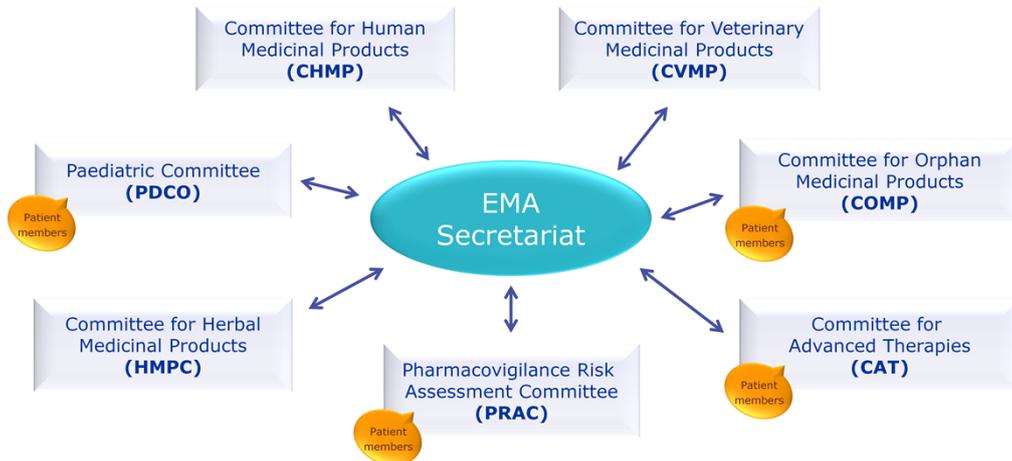
In some cases, they represent patients organisations in general such as members of the management board and some of the Agency's scientific committees

For other activities they represent their OWN organisations such as within the Patients and Consumers Working Party, throughout different consultations and also within workshops...

Importantly, patients are also involved as INDIVIDUAL experts and this is within the evaluation of specific medicines and we will talk more about this later .....

## Patients on EMA scientific committees

Patient members of the EMA committees are nominated by the European Commission in consultation with the European Parliament

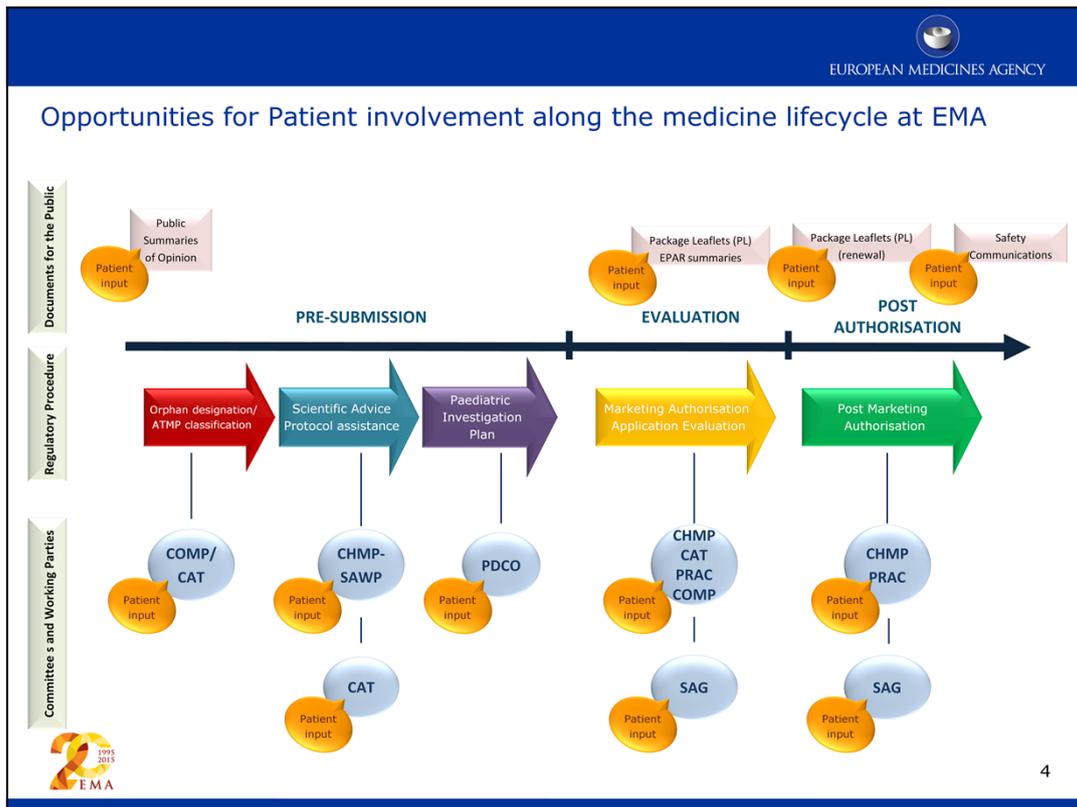


Of the 7 committees that evaluate medicines at the EMA – 6 are for human medicines and one is for veterinary,

Patients are full members of four of these committees

These are the orphan, paediatric, advanced therapy and pharmacovigilance committees...

When we say full members, this means that they have full voting rights and participate as any other member...



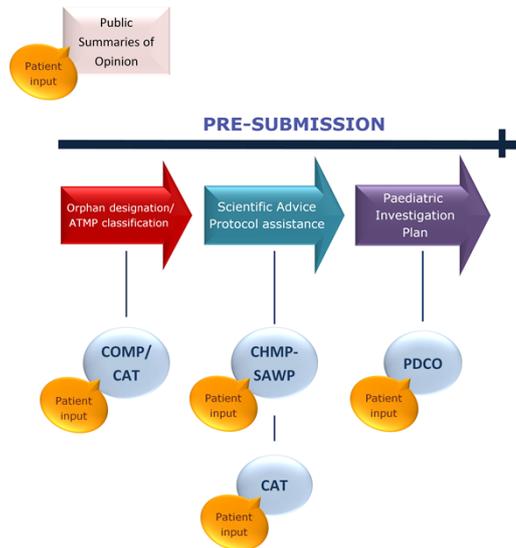
This diagram shows an overview of the medicines regulatory pathway and you can see that it is split into Pre-Submission, Evaluation and Post-Authorisation.

Pre-submission is before the company submits an application for marketing authorisation and will include procedures such as requests for orphan designation, evaluation of paediatric investigation plans and classification of advanced therapies.. (you can find more information on all these procedures on our website).

Evaluation relates to once the company has submitted their application and post-authorisation, once the medicine has received approval for marketing from the European Commission..

Here we see where patients are involved throughout all of these procedures...

## Pre-Submission Opportunities for Patient involvement at EMA



Patients are involved in pre-submission activities at the EMA via:

- **Membership** of scientific committees
- **Participation** in [Scientific Advice \(Protocol Assistance\)](#) procedures
- **Consultation** by Committees on specific medicines
- **Review** of [Public Summaries of Orphan Designation](#)

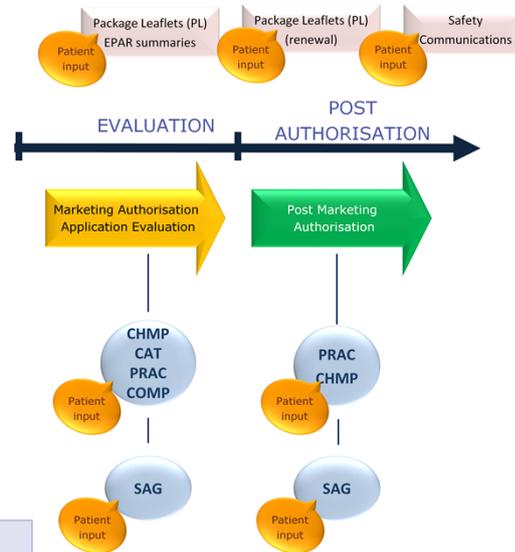
**More information:** *How patients are involved in EMA scientific discussions* [video](#) 5

If we take the pre-submission phase, patients are involved in committees, in scientific advice procedures where we provide advice to companies on their development plans, they can also be consulted by any of the committees on specific medicines and they also systematically review the summaries on orphan designation that are written for the public.

## Evaluation and Post-authorisation opportunities for Patients at EMA

Patients are involved in evaluation and post-authorisation activities at the EMA via:

- **Membership** of scientific committees
- **Participation** in [Scientific Advisory Groups \(SAG\)](#) or ad hoc Expert Groups
- **Consultation** by Committees on specific medicines
- **Review** of Package Leaflets , [EPAR summaries](#) and Safety Communications



**More information:** *How patients are involved in EMA scientific discussions* [video](#)



For the evaluation and post-authorisation phases; in addition to membership of the committees as already mentioned, patients are also invited to participate in any scientific expert meetings that are convened to discuss ongoing evaluations on specific medicines as well as written consultations.

They also review all of the package leaflets, European Public Assessment Report (or EPAR) summaries and safety communication documents to ensure that they are clear and written appropriately for the target audience..



## Patients and Consumers Working Party (PCWP)

The PCWP plays a key role in the interaction between the EMA and patient organisations. Platform for dialogue and exchange on relevant issues concerning medicines;

The PCWP provides recommendations to the EMA and its Human Scientific Committees on all matters of direct or indirect interest to patients and consumers

Members representing:

- Patients' and Consumers' Organisations
- EMA Scientific Committees

Observers from:

- Management Board
- European Commission



Photo credit: Roberto De Lisa (EMA)



The EMA has also set up a working party of patients and consumers organisations, in 2006. This serves as the key platform for exchange of information with these stakeholders...

Membership of the working party includes, patients and consumers organisations, members of the scientific committees and observers from the management board and European Commission

These meetings are often held jointly with the healthcare professionals working party as there are many areas of common interest

They meet 4 times a year at the EMA offices in London but they are also consulted on many of the Agency's policies and other activities at any time when it is necessary.

To learn more about the PCWP, please watch the video on this topic

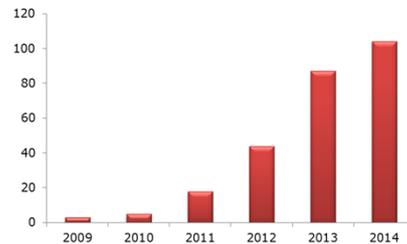


## Other activities

Patients are frequently invited to participate in EMA **conferences and workshops**.

The Agency strives to ensure that patients are given opportunities to participate (as speakers, chairs....) as often as possible.

Involvement of patients in workshops (2009-2014)



Patients also contribute to **EU-wide initiatives** where EMA is involved such as:

- [Enpr-EMA](#) - European Network of Paediatric Research at the European Medicines Agency
- [ENCePP](#) - European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
- [WEB-RADR](#) - Recognising Adverse Drug Reactions



Patients are also involved in a lot of other activities such as at the EMA, for example the conferences and workshops where they are frequently invited as speakers.

Patients also contribute to many of the EU wide initiatives where EMA is involved such as the network of paediatric research, the network that looks at safety data and also WEB-RADR which looks at ways of capturing that data.



## Why is patient involvement important to EMA?

- They know more about *living with the disease* as a patient or carer than the medical or scientific experts
- They are familiar with the *needs* of patients and families in the community
- They know how the diseases are managed, what the treatment options and unmet needs are
- They understand the reality of the *feasibility* of clinical investigations



So why is patient involvement important to the EMA?

Patients know about living with the disease, they are familiar with the needs of the patients and the family in the community and they know what it is like to live with the disease on a daily basis.

They know how the diseases are managed, what treatment options they have and what are the needs that are unmet.

They also understand what would be realistically feasible in a clinical trial design.

## Involvement of patients at EMA

- Patients are a recognised and integral part of the Agency's work
- Their involvement has brought everyday aspects of living with a disease into scientific discussions and improved the quality of patient information and communication on medicines.



This has been a collaborative journey with many stakeholders, cultures and languages and has had its challenges.

Our experience has shown that the different perspectives are essential and have ultimately resulted in more meaningful decisions for all concerned.



**More information:** available in the Annual Reports published by EMA and available [here](#).

As you have seen, patients are an integral part of the Agency's work and their contributions have brought the everyday aspects of living with the disease into the scientific discussions.

This has ultimately resulted in more meaningful decisions for all concerned...



Input from patients is another part of the puzzle and completes the picture....



Like all other experts, patients have a seat at the table and their contributions are an essential part of the puzzle...



## Training and Support

To support the participation of patients in activities across the Agency, the Patients and Healthcare Professionals Department has prepared material such as videos and supporting documents as well as a Patients' Manual to facilitate and optimise their involvement.

To find this information, please click on the link to the [Patients and Consumers' section](#) of the EMA website – "Training and Support" page.



To ensure that we support the participation of patients across all these activities, the Department has prepared material such as videos and supporting documents as well as a patients manual so we can be sure that we can facilitate and optimise their involvement.



## Contact



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