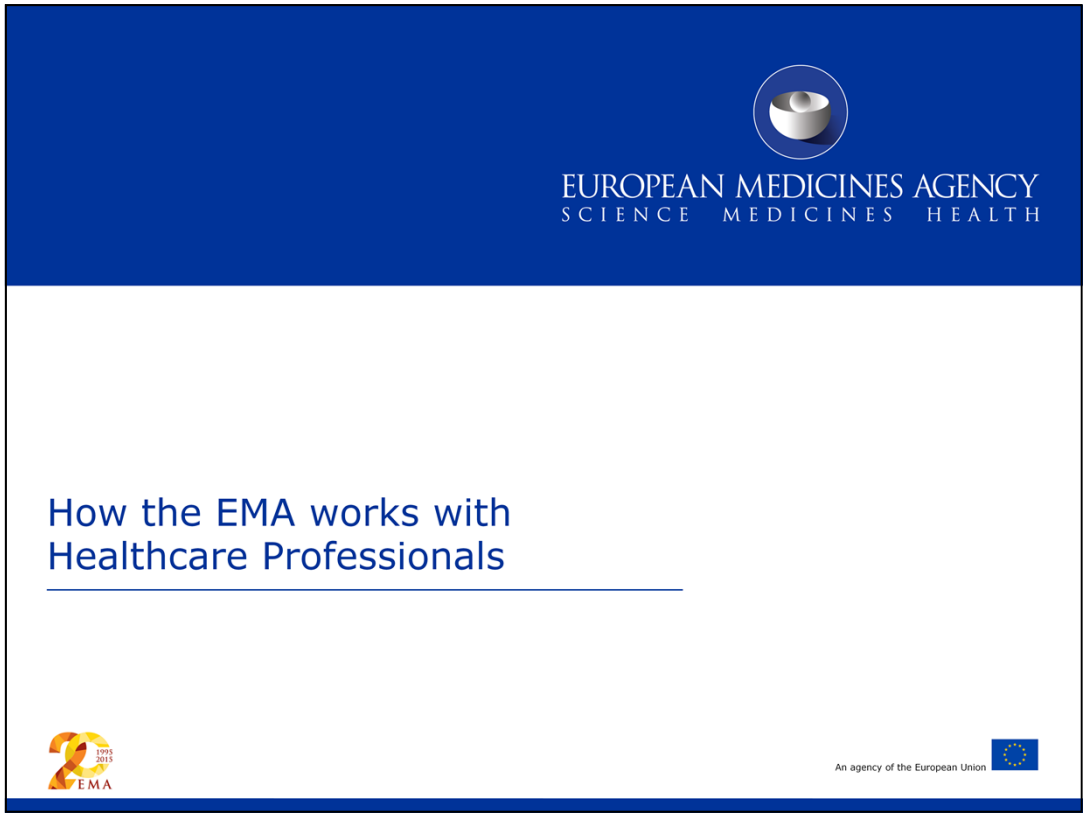
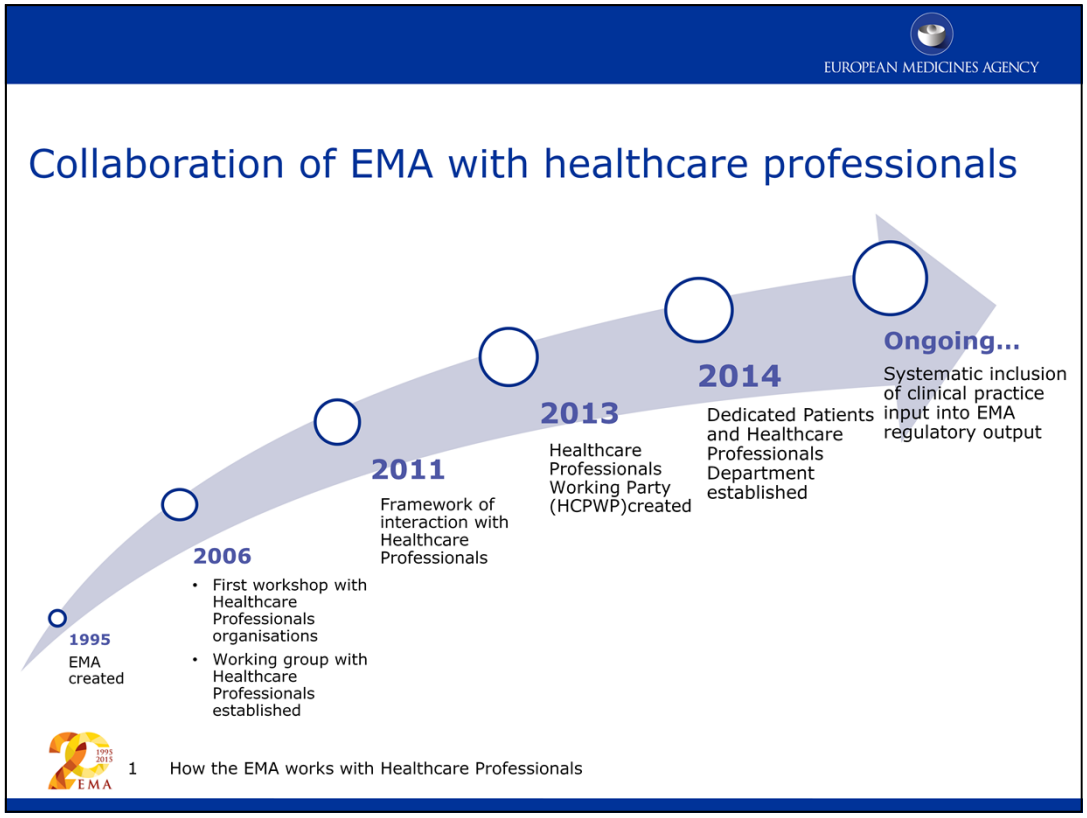


In this video, we are going to tell you about how the European Medicines Agency interacts with Healthcare Professionals

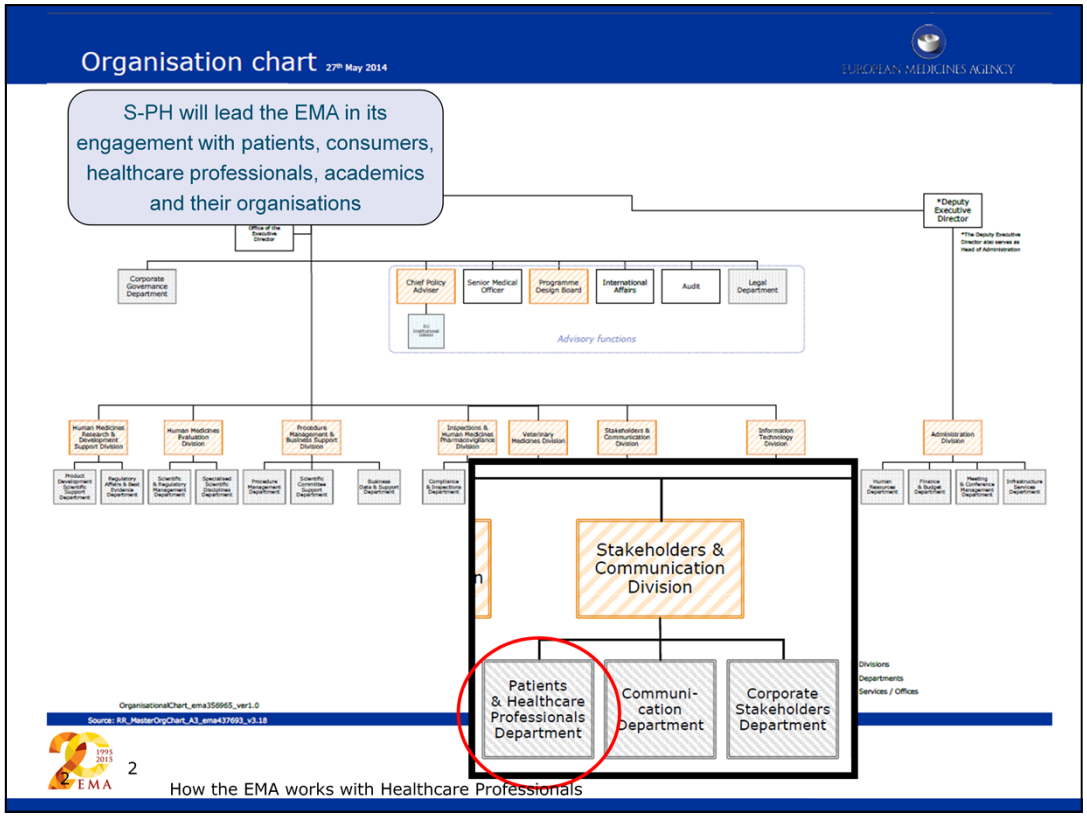


The EMA was created in 1995 and has since collaborated very closely with healthcare professionals in many aspects of its work

The Agency recognised the importance of working with the wider community of medical specialists, general practitioners, pharmacists and nurses to bring their perspective of clinical practice into EMA discussions.

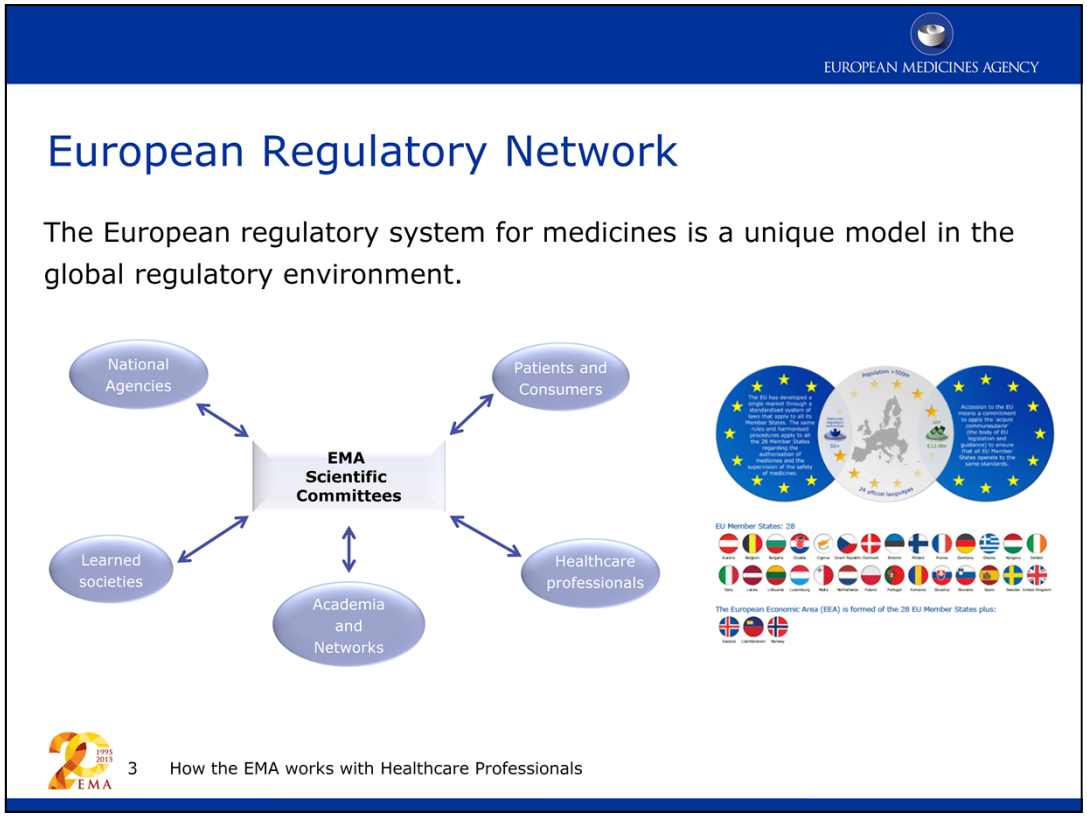
In 2006, the first workshop with healthcare professionals was organised at the EMA followed by the creation of a working group. In 2011, to build on its experience with Patients and Consumers, the EMA developed a specific Framework for interaction with healthcare professionals.

This was followed in 2013 by the establishment of the official Healthcare Professional Working Party. As you will learn more about in this video, the real life clinical experience of healthcare professionals is now systematically included in EMA regulatory outputs.



Recognising the importance of communicating and collaborating with its stakeholders, the EMA established a Stakeholders and Communication Division.

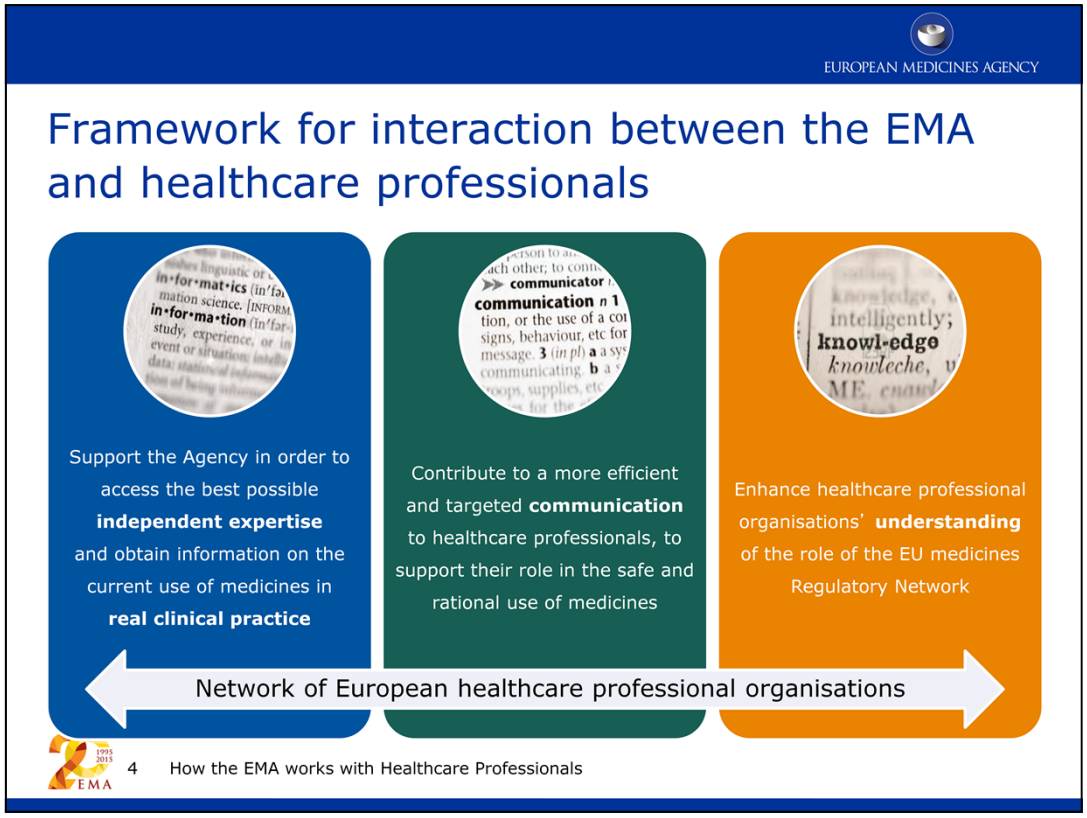
Within this division there is a dedicated Department for working with Patients and Healthcare Professionals.



The European medicines regulatory network is a collaborative model and brings together **28 Member States** in an effective way to regulate medicines;

This model is the basis of the Agency's success as it provides access to a **pool of experts from across the EU**, allowing it to source the **best-available scientific expertise**

These experts include the members of the national competent authorities, learned societies, academia, patients and of course healthcare professionals, all of whom contribute in various ways to the work of the EMA scientific committees.



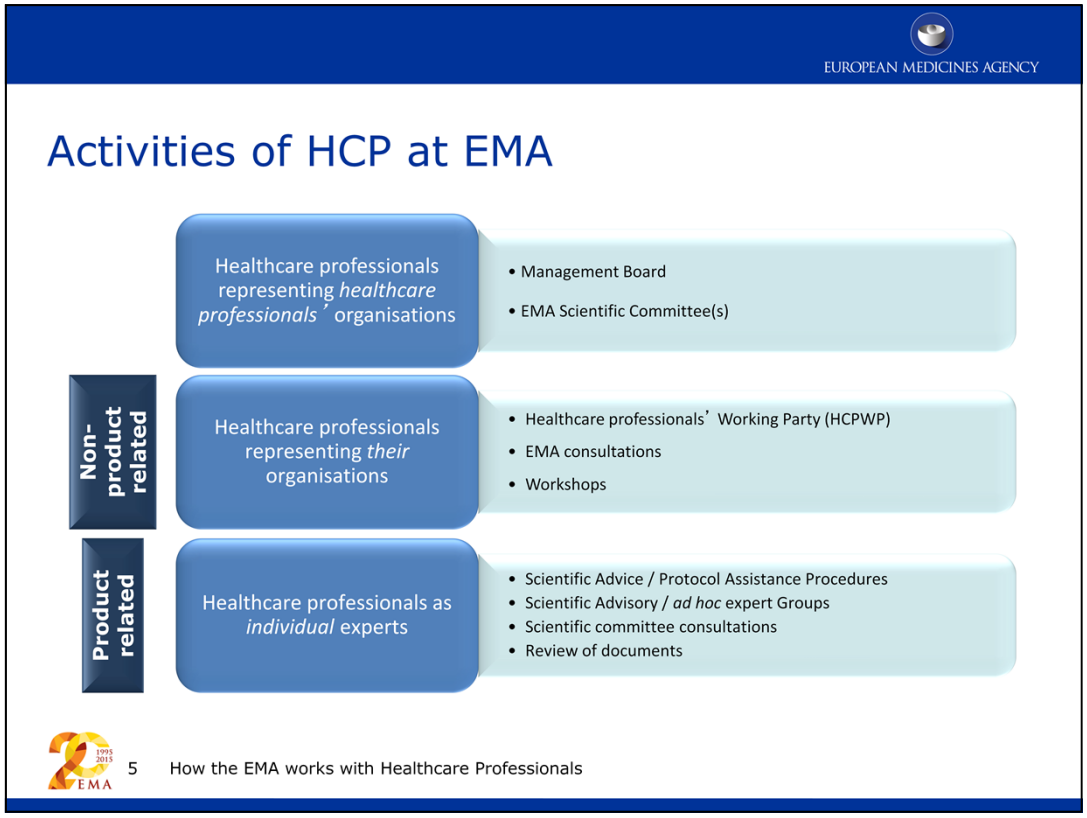
The framework for interaction between EMA and Healthcare Professionals was a key milestone to further structure the existing collaboration with healthcare professionals and their representative organisations.

As you can see here, the main goals of the framework are to support the Agency in order to access the best possible **independent expertise** in any matter related to medicines; contribute to a more efficient and targeted **communications**; and to enhance healthcare professional organisations' **understanding** of the role of the European medicines Regulatory Network.

In this spirit, the framework aims to support and reinforce knowledge that exists in this Network with additional valuable input from day-to-day clinical practice while enhancing communication and outreach to those impacted by EU decisions.

It recognises healthcare professional organisations' including learned societies as key facilitators to channel inputs from and outputs to the wider community of healthcare professionals

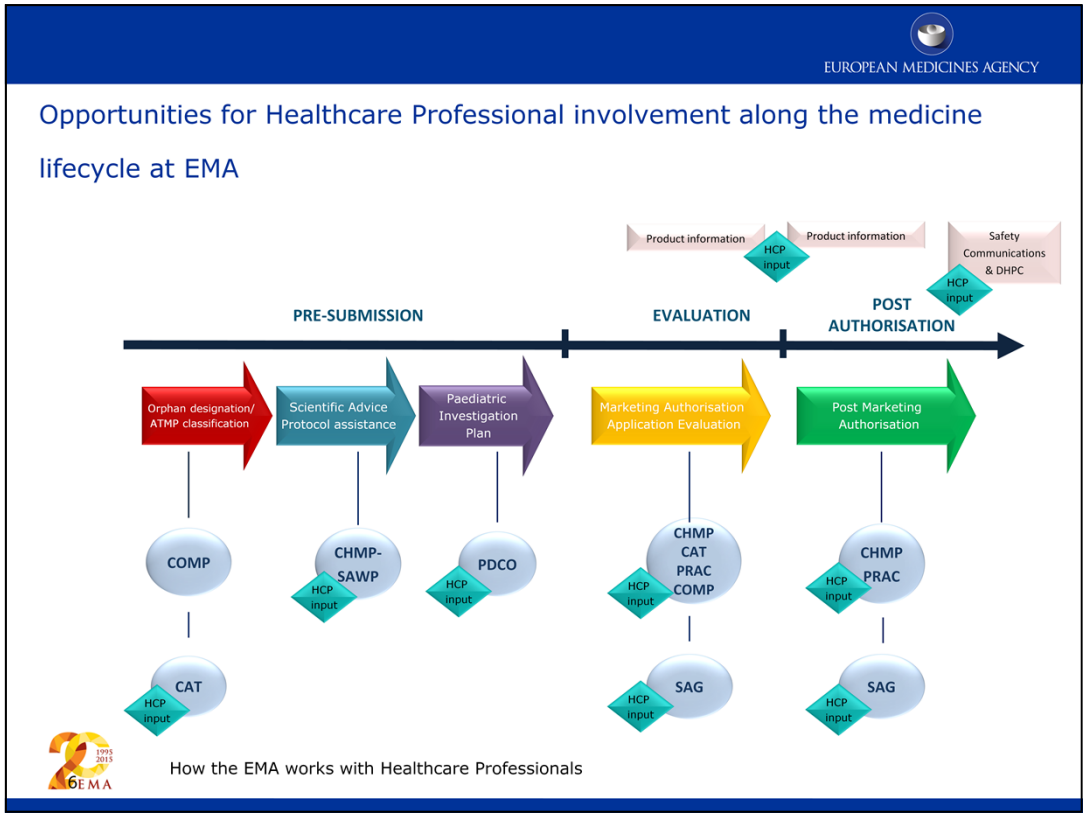
Let us now focus on the ways in which healthcare professionals are involved at the EMA.



In some cases, they represent healthcare professionals' 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 Healthcare Professionals Working Party, throughout different consultations and also within workshops…

Importantly, healthcare professionals are also involved as INDIVIDUAL experts and this is within the evaluation of specific medicines



This diagram shows and 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 healthcare professionals are involved throughout all of these procedures…

And Which organisations do we work with?

In fact, any organisation representing EU healthcare professionals can express an interest to work with the Agency and as long as they meet defined eligibility criteria, then the EMA very much welcomes their participation.

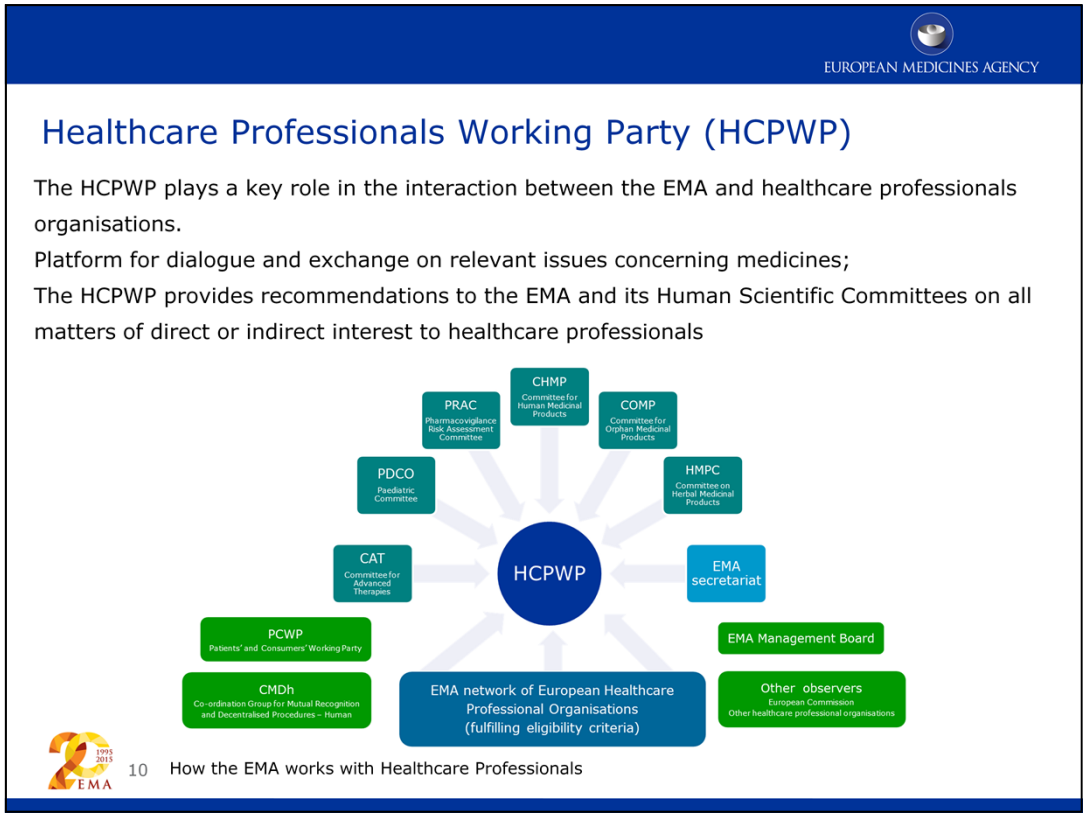
The list of these eligible organisations can be found on our website and we now have a large network across the European Union.

The network of eligible organisations is one of the pillars of the framework of interaction and it is from amongst these organisations that the members of the Healthcare Professionals Working Party are selected.

EUROPEAN MEDICINES AGENCY

The Healthcare Professionals Working Party

Here is a photo of the Working Party



The working party (or HCPWP) plays a key role in the Agency's interaction with healthcare professionals' organisations, it is the platform where they can exchange information and talk about issues of common interest, within the remit of the Agency's responsibilities.

The working party helps provide recommendations to the EMA and its scientific committees on all aspects related to medicines.

The members of the HCPWP represent the eligible organisations but there are also representatives from the scientific committees and additionally observers from the EMA Management Board and the European Commission.

The working party meets 3 times a year, they have plenary meetings as well as joint meetings with the Patients and Consumers working party.

If you would like to learn more about the Healthcare Professionals' Working Party at the EMA or any other aspects of healthcare professional involvement, please don't hesitate to visit our website: www.ema.europa.eu

In accordance with the transparency initiative of the EMA, agendas, minutes and recordings of meetings (where available) are all published on our website.