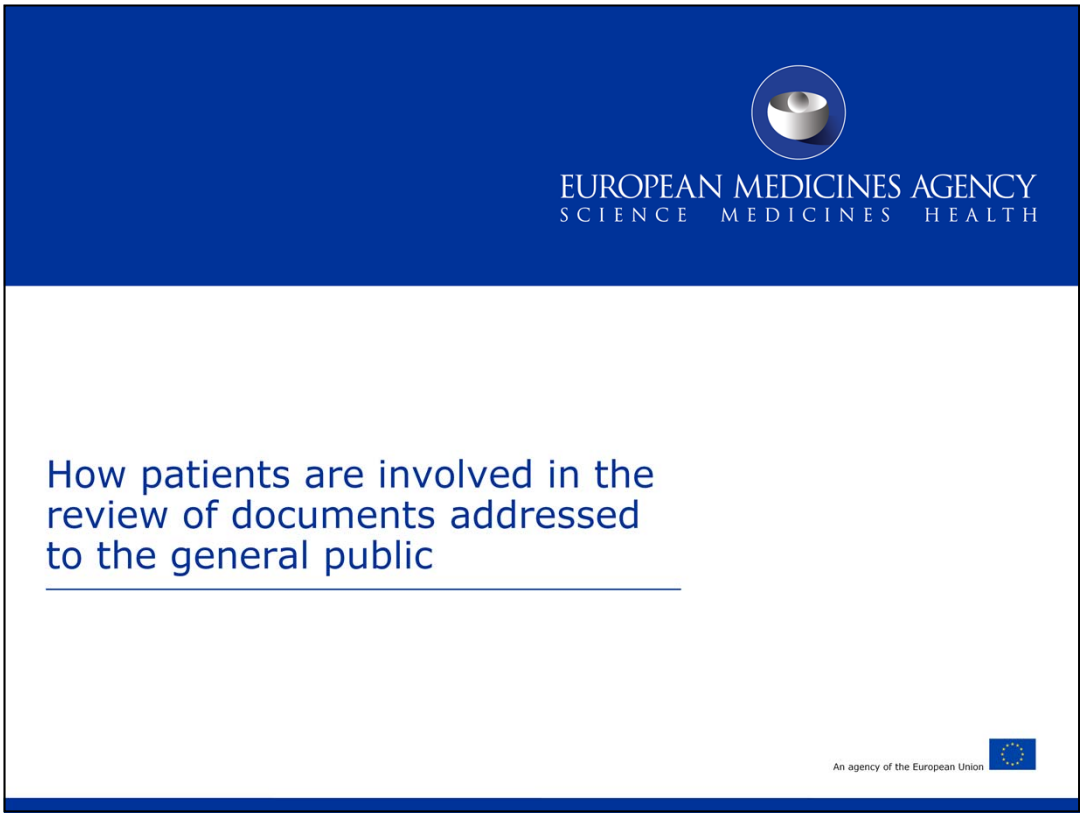
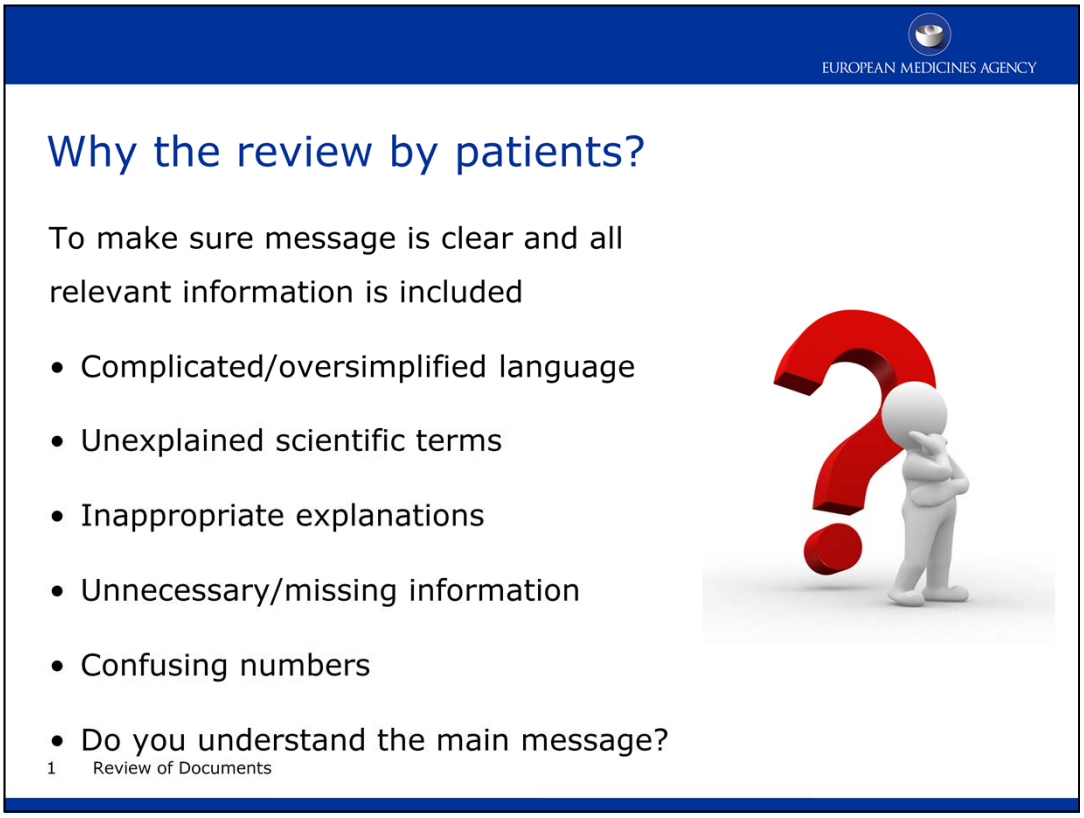


In this video we are going to describe several documents that are addressed to the general pubic and how patients are involved in reviewing them.



Why do we ask patients to review our documents?

Patient review helps us to ensure that the message is clear to patients and that all relevant information is included.

For example, we want to make sure that the language used is appropriate and the scientific terms used are well explained. Also, we would like to know if there is too much information or if any information that is important to the patient is missing. Are the numbers confusing? Do you understand the main message?

When documents are meant for a particular audience it is crucial to have their input. We conduct numerous consultations with patients and consider all their comments when writing documents addressed to them.

EUROPEAN MEDICINES AGENCY

Which documents are reviewed by patients?

- European public assessment report (EPAR) summaries
- Package leaflets (PL)
- Safety communications
- Herbal summaries

The documents currently reviewed by patients are EPAR summaries, Package Leaflets, Safety Communications and Herbal Summaries, and we will now describe them individually.

EUROPEAN MEDICINES AGENCY

European Public Assessment Report (EPAR) summary

- Once a medicine is approved, information about the medicine is published in the form of an EPAR or European public assessment report.
- An EPAR summary is a public-friendly summary in question-and-answer format explaining what the medicine is for and how it came to be approved.

After a medicine is approved, we publish information about the medicine in the form of an EPAR or European Public Assessment Report.

An EPAR summary is a short summary of this information for the general public in non-technical language. It explains what the medicine is for and why the Agency recommended its approval.

EUROPEAN MEDICINES AGENCY

European Public Assessment Reports (EPAR) summary

- Required by EU law for all centrally authorised medicines
- Drafted by EMA
- Reviewed by EMA staff and experts, patients and the pharmaceutical company
- Translated into all official EU languages

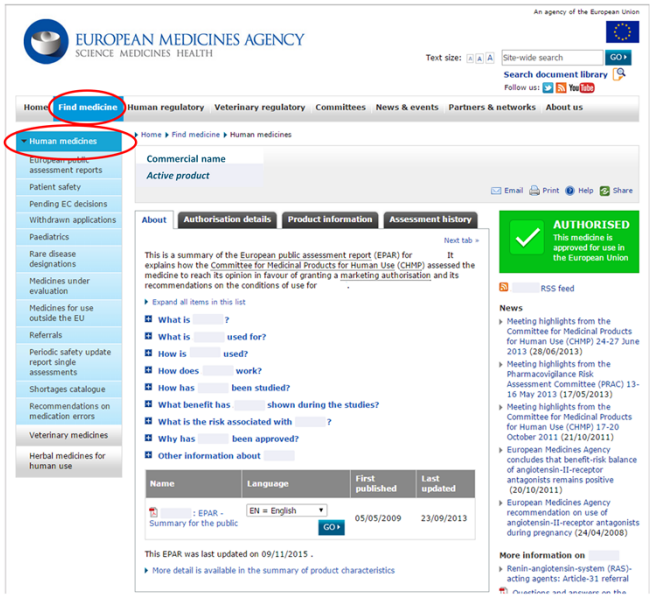
EPAR summaries are required by EU law for all centrally authorised medicines.

Once we draft the summary, we have it reviewed by our experts and then by patients. We then send the summary to the pharmaceutical company for their information.

We translate the final draft into all official EU languages.

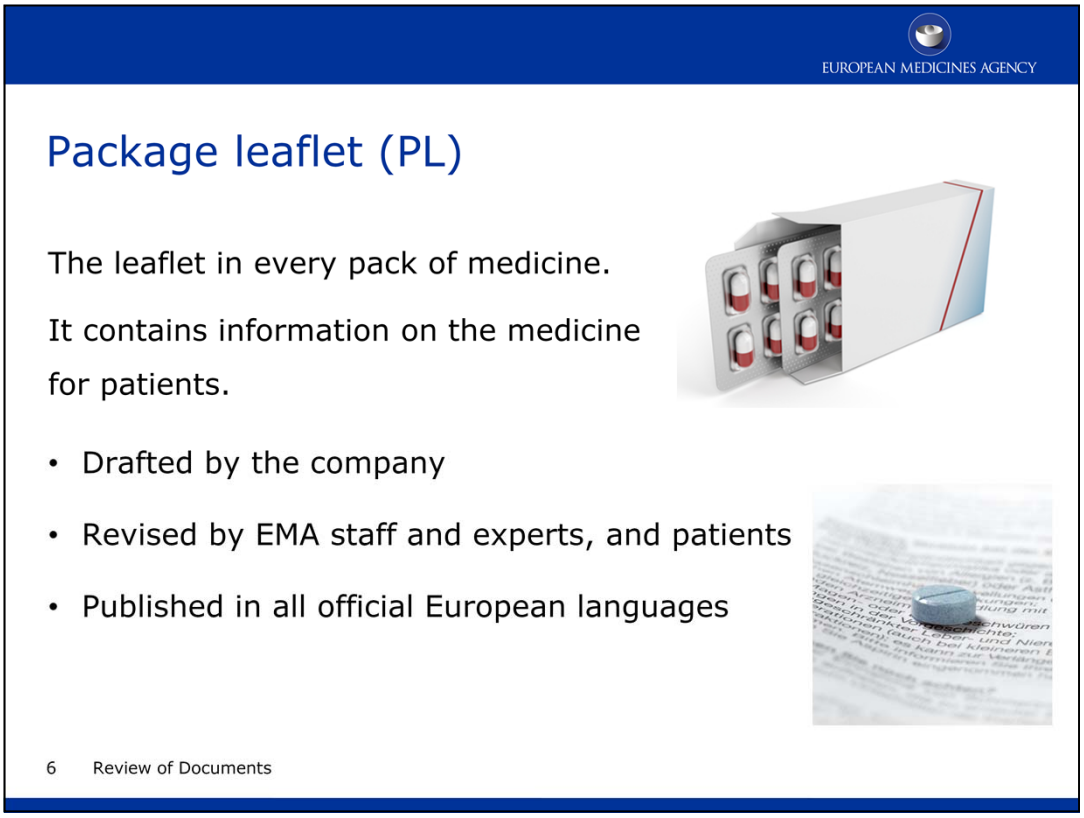
EUROPEAN MEDICINES AGENCY

Where can you find EPAR summaries?



1. Go to EMA website (www.ema.europa.eu)
2. Type medicine name in 'Find medicine' search box
3. EPAR summary is the landing page, also available in pdf format

To find the EPAR summary of a medicine you are interested in, go to EMA's homepage and type the medicine's name in the 'find medicine' search box.



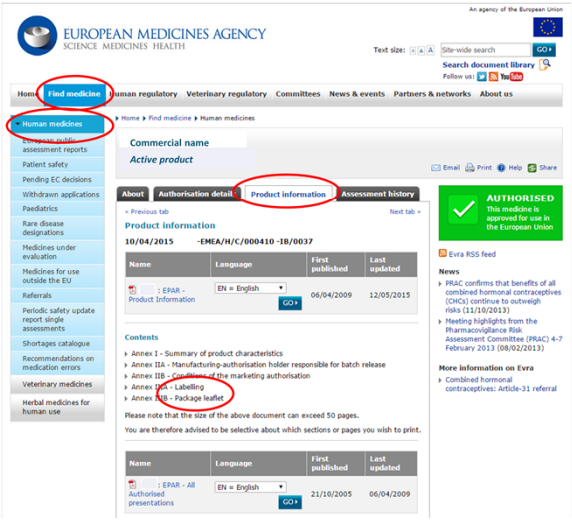
The Package Leaflet is the document you find in the medicine pack and provides information in non-technical language for patients about its use.

The pharmaceutical company prepares the package leaflet and sends it to us for approval. During our review of the leaflet, we send it to patients and take their comments into account.

The final draft of the package leaflet is also available on EMA's website in all official European languages.

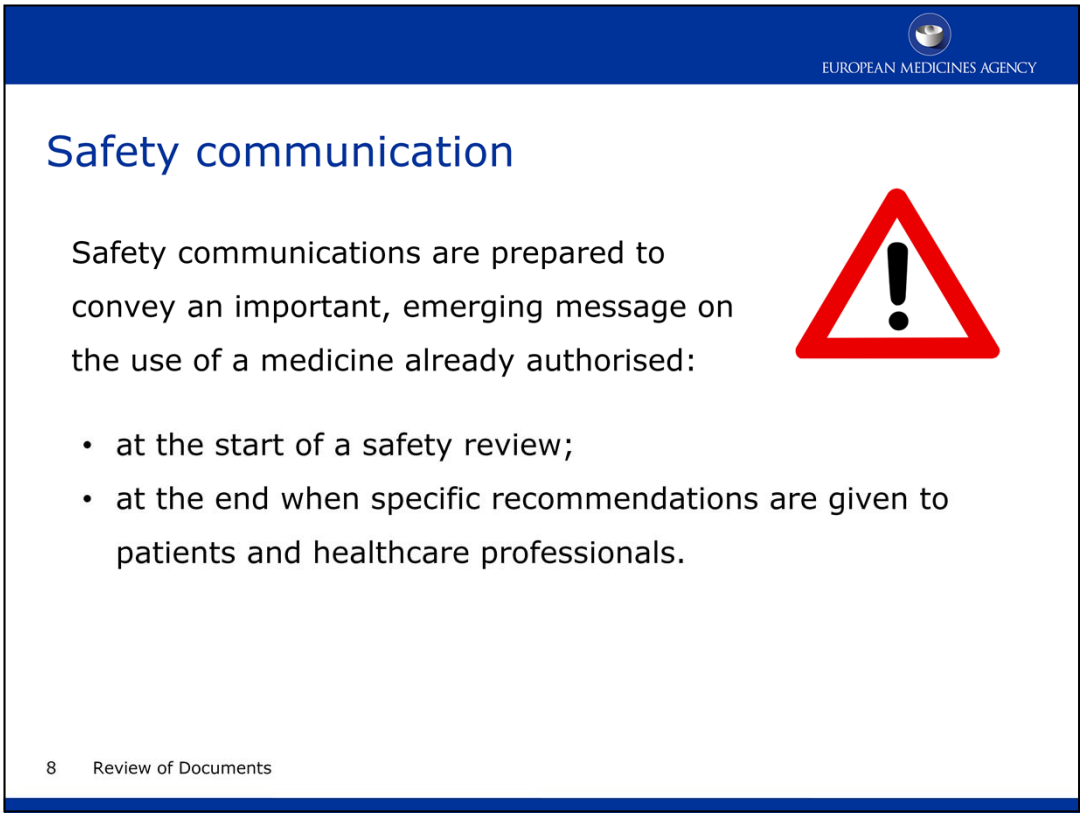
EUROPEAN MEDICINES AGENCY

Where can you find the package leaflet?



1. Go to EMA website (www.ema.europa.eu)
2. Type medicine name in 'Find medicine' search box
3. Click on 'Product information' tab

The package leaflet is published on the same page as the EPAR summary and can be found under the tab 'product information'.



Safety communication documents are used to convey important information about the risks of a medicine, for example if we discover a new serious side effect or when a known side effect is more serious than we previously thought.

In some cases, we publish a safety communication to announce that we have started a review of a new risk. We also publish these at the end of important reviews, particularly when we have advice for patients and healthcare professionals.

EUROPEAN MEDICINES AGENCY

Safety communication

- Drafted by EMA
- Reviewed by EMA staff and experts, patients and healthcare professionals and pharmaceutical company
- First published in English and later translated into all official European languages

As with EPAR summaries, we send safety communications to patients for review. In addition, we also send a draft to healthcare professionals.

The pharmaceutical company gets a copy for their information.

The final version is then published in English and later translated into all official EU languages.

EUROPEAN MEDICINES AGENCY

Herbal summaries

- EMA's Committee on Herbal Medicinal Products (HMPC) is responsible for giving recommendations on the medicinal uses of herbal substances.
- EU Member States will take these recommendations into account when approving herbal medicines in their territories.
- Herbal summaries are public-friendly summaries of the HMPC recommendations.

The Committee on Herbal Medicinal Products at EMA is responsible for giving recommendations on the medicinal uses of herbal substances on the basis of the evidence available.

Although herbal medicines are usually approved nationally, national authorities take the Herbal Committee recommendations into account when approving herbal medicines.

Herbal summaries explain what these recommendations are and they are written for the general public.

EUROPEAN MEDICINES AGENCY

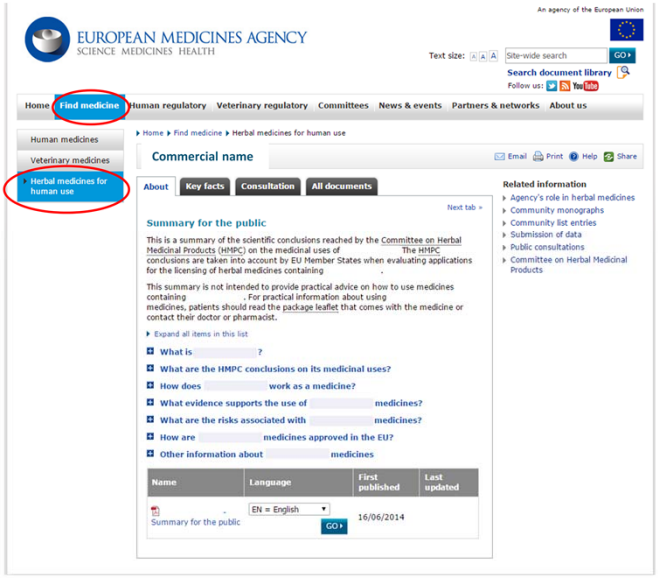
Herbal summaries

- Drafted by EMA
- Reviewed by EMA staff and experts, as well as patients
- Published in all official European languages

Herbal summaries are also reviewed by patients and published in all official EU languages.

EUROPEAN MEDICINES AGENCY

Where can you find herbal summaries?

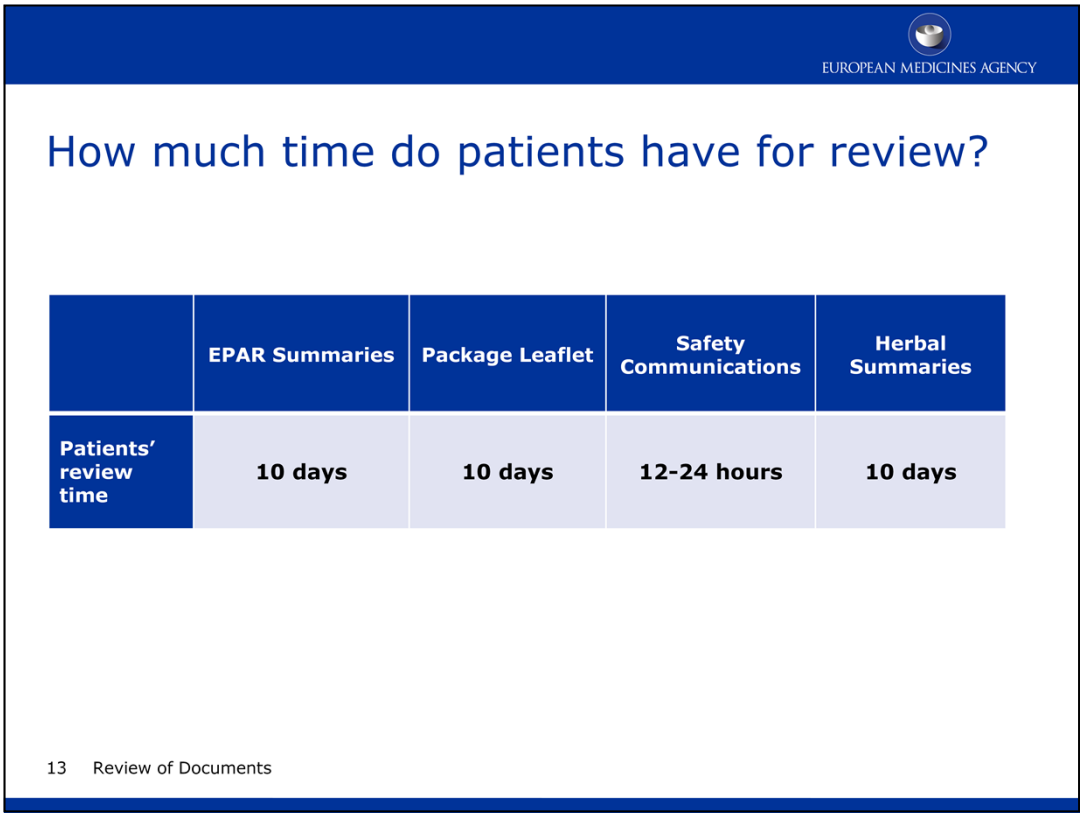


Type herbal medicine name in 'Find medicine' search box on EMA homepage

or

Click on the 'Find medicine' tab and then on the tab 'Herbal medicines for human use'

To find an herbal summary, you can either type the name of the herbal substance in the 'find medicine' search box on EMA's homepage or click on the 'find medicine' tab and then on the tab 'herbal medicines for human use'.



So, how much time do patients have to review documents?

For EPAR summaries, package leaflets and herbal summaries, which are planned well in advance and follow strict timetables, patients can get up to 10 days to review the documents.

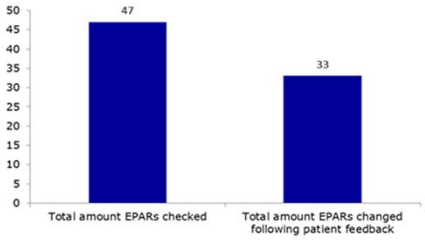
For safety communication, which can be written on very short notice, we may have to ask for comments much earlier, sometimes within as little as 12 to 24 hours. We always try to give patients as much time as possible.

EUROPEAN MEDICINES AGENCY

The importance of the review by patients

- Patients unique perspective
- Patients and public concerns
- Appropriate use of language

Patient involvement improves quality. In 2015, 70% of suggestions made for EPAR summaries led to changes



14 Review of Documents

To conclude, patients' contribution is of real added value because patients can give us a view point that no one else can offer. They can advise on any particular concern with a medicine or a condition we may not be aware of and of course give us feedback on whether the language used is clear and appropriate. All this contributes to the quality of the documents we produce.

In 2015, 70% of the comments received from patients on EPAR summaries were incorporated into the final document.

EUROPEAN MEDICINES AGENCY

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