



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## How patients are involved in the review of documents addressed to the general public

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An agency of the European Union 

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



## Why the review by patients?

To make sure message is clear and all relevant information is included

- Complicated/oversimplified language
- Unexplained scientific terms
- Inappropriate explanations
- Unnecessary/missing information
- Confusing numbers
- Do you understand the main message?



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.



## 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 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 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.

## Where can you find EPAR summaries?

The screenshot shows the EMA website interface. At the top, there is a navigation bar with 'Find medicine' highlighted in red. Below this, a search box is visible with the text 'Search document library'. The main content area displays the EPAR summary for a medicine, including a green 'AUTHORISED' badge and a table with columns for Name, Language, First published, and Last updated. The table shows 'EPAR - Summary for the public' in English, first published on 05/05/2009 and last updated on 23/09/2013.

1. Go to EMA website ([www.ema.europa.eu](http://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.



## Package leaflet (PL)

The leaflet in every pack of medicine.

It contains information on the medicine for patients.



- Drafted by the company
- Revised by EMA staff and experts, and patients
- Published in all official European languages



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.

## Where can you find the package leaflet?

The screenshot shows the EMA website interface. At the top, there is a search bar and navigation links. The 'Find medicine' link is highlighted with a red circle. Below the navigation bar, the 'Human medicines' menu is also circled in red. The main content area shows the 'Product information' tab selected, with a red circle around the 'Package leaflet' link under 'Annex IB'.

1. Go to EMA website ([www.ema.europa.eu](http://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

Safety communications are prepared to convey an important, emerging message on the use of a medicine already authorised:



- at the start of a safety review;
- at the end when specific recommendations are given to patients and healthcare professionals.

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.



## 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.



## 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.



## 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.

## Where can you find herbal summaries?

The screenshot shows the EMA website interface. At the top, there is a navigation bar with the following tabs: Home, Find medicine, Human regulatory, Veterinary regulatory, Committees, News & events, Partners & networks, and About us. The 'Find medicine' tab is circled in red. Below this, there is a sub-menu with 'Human medicines', 'Veterinary medicines', and 'Herbal medicines for human use'. The 'Herbal medicines for human use' option is also circled in red. The main content area shows a search box for 'Commercial name' and a 'Summary for the public' section. The summary text includes: 'This is a summary of the scientific conclusions reached by the Committee on Herbal Medicinal Products (CHMP) on the medicinal uses of... The CHMP conclusions are taken into account by EU Member States when evaluating applications for the licensing of herbal medicines containing... This summary is not intended to provide practical advice on how to use medicines containing... For practical information about using medicines, patients should read the package leaflet that comes with the medicine or contact their doctor or pharmacist.' Below the summary, there are several expandable sections: 'What is...', 'What are the HMP conclusions on its medicinal uses?', 'How does... work as a medicine?', 'What evidence supports the use of... medicines?', 'What are the risks associated with... medicines?', 'How are... medicines approved in the EU?', and 'Other information about... medicines'. At the bottom, there is a table with columns for 'Name', 'Language', 'First published', and 'Last updated'. The table contains one entry: 'Summary for the public' with 'EN = English' in the language column and '16/06/2014' in the last updated column.

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'

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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'.



## How much time do patients have for review?

	EPAR Summaries	Package Leaflet	Safety Communications	Herbal Summaries
Patients' review time	10 days	10 days	12-24 hours	10 days

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

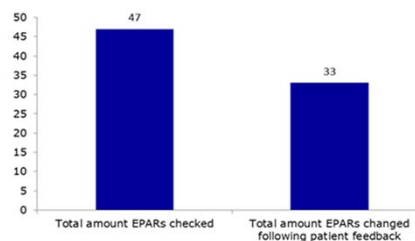
For EPAR summaries, package leaflets and herbal summaries, which are planned well in advance and follow strict timetables, patients can get up to 10 days to review the documents.

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.

## 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



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.



## Contact



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