

# Overview of patient involvement in EMA public communications

Joint CTTI/FDA Patient Engagement Collaborative and EMA Patient and Consumer Working Party Meeting

1 July 2021





#### Documents reviewed by patients

Document	Review time			
Medicine overviews*	8-10 days			
Safety communications*	12-24 hours			
Package leaflets	10 days			
Herbal summaries	10 days			



#### What is EMA looking for in the review?

We want reviewers to tell us if:

- The document is clear
- There is complicated/oversimplified language
- There is important information missing
- The numbers and scientific data (such as study findings) make sense



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#### Medicine Overview

- European Public Assessment Report (EPAR): details of the scientific assessment of an authorised medicine
- Medicine Overview: a public-friendly version, based on the EPAR, explains in Q&A format what the medicine is and how it came to be authorised.



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#### Safety communication

Safety communications convey important, emerging messages on the use of authorised medicines:

- at the start of a safety review to alert to a potential concern;
- at the end with specific recommendations for patients and healthcare professionals.



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#### Example

#### What is the risk associated with Halaven?

The most common side effects with Halaven (seen in more than 1 patient in 10) are neutropenia (low levels of neutrophils, a type of white blood cell that fights infection), leucopenia (low white blood cell counts), anaemia (low red blood cell counts), reduced appetite, peripheral neuropathy (damage to the nerves in the extremities), headache, nausea (feeling sick), constipation, diarrhoea, vomiting, alopecia (hair loss), muscle and joint pain, fatigue (tiredness) and pyrexia (fever). For the full list of all side effects reported with Halaven, see the package leaflet.

Halaven should not be used in people who may be hypersensitive (allergic) to <u>eribulin</u> or any of the other ingredients. It must not be used in women who are breastfeeding.

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(feeling sick), constipation, diarrhoea, vomiting, alopecia (hair loss), muscle and joint pain, fatigue (tiredness) and pyrexia (fever). For the full list of all side effects reported with Halaven, see the package leaflet.

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**Comment [PE6]:** What would be the effect on the patient? Pain?, tingling, numbness? I think that <u>cn</u> be added to make it more clear to the patient what it means.

Comment [NM(7]: More explanation added: causing numbness, tingling and prickling sensations



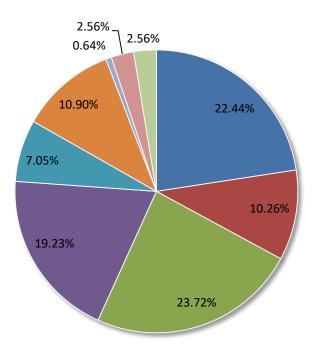
#### To take in review comments, we consider:

- how the change affects other parts of the document
- if others have commented on the same wording
- if the suggestion demands a high level of technical knowledge on the reader's part
- if the suggestion affects standard (and pre-translated) wording

A suggestion might not lead to immediate change but may be considered for our periodic review of the template.



#### Patient review, impact and feedback





- 2 How is it used
- 3 How does it work
- 4 Benefits
- 5 Risks
- 6 Why is it introduced
- 7 Awaited info
- 8 Safety measures
- 9 Other info

### Impact of review

50% of changes proposed incorporated into final documents

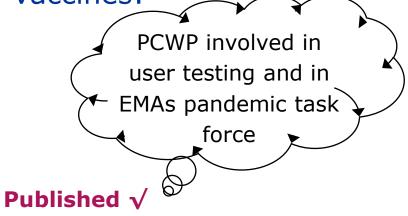
#### Feedback

Provided on documents such medicine overviews, safety communications and herbal summaries



### Information materials on COVID-19 vaccines: Key facts

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EUROPEAN MI SCIENCE MEDICINES	EDICINES AGENCY Search				
Medicines 🗸 Human regulato	ry Veterinary regulatory 🗸 Committees 🗸 News & events 🗸 Partners & networks 🗸 About us 🗸				
Human regula	atory				
Overview	Research and development Marketing authorisation				
Post-authorisation	Herbal products				
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certification Public health threats 🗸	The European Commission has authorised the first vaccines to prevent COVID-19 in the European Union (EU), following evaluation by the European Hedicines Agency (ENA). EMA is liaising closely with developers of other potential COVID-19 vaccines, mobilising its own resources and cooperating with regulatory partners, to ensure selfs and effective vaccines				
Coronavirus disease	reach patients as soon as possible.				

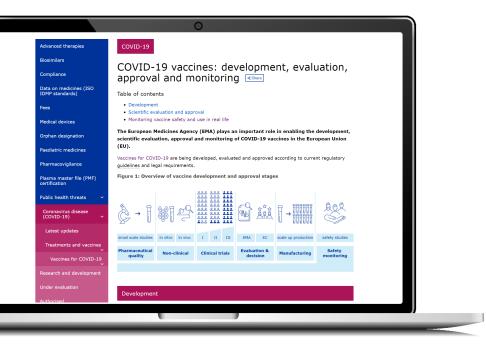


- Questions and answers format
- General public
- · Addresses commonly received questions





#### Information materials on COVID-19 vaccines: Development, evaluation, approval and monitoring



#### Published $\sqrt{}$

- More detailed information on how COVID-19 vaccines are developed, evaluated, approved and monitored post-marketing
- Professional audiences and general public
- Addresses commonly received questions
- Graphics to illustrate concepts





## Any questions?

#### Further information

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