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

1 Overview of patient involvement in EMA public communications

What is EMA looking for in the review?

We want reviewers to tell us if:

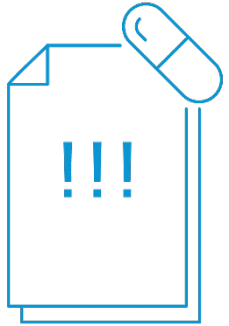
- The document is clear
- There is complicated/oversimplified language
- There is important information missing
- The numbers and scientific data (such as study findings) make sense

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.

Medicine overview: Drafted by EMA medical writers → Reviewed by EMA staff/CHMP member → Reviewed by patients → Shared with the pharmaceutical company → Translated into all official EU languages

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.

Example

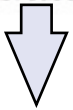
What is the risk associated with Halaven?

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 eribulin or any of the other ingredients. It must not be used in women who are breastfeeding.

Comment [PE6]: What would be the effect on the patient? Pain?, tingling, numbness? I think that cn 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



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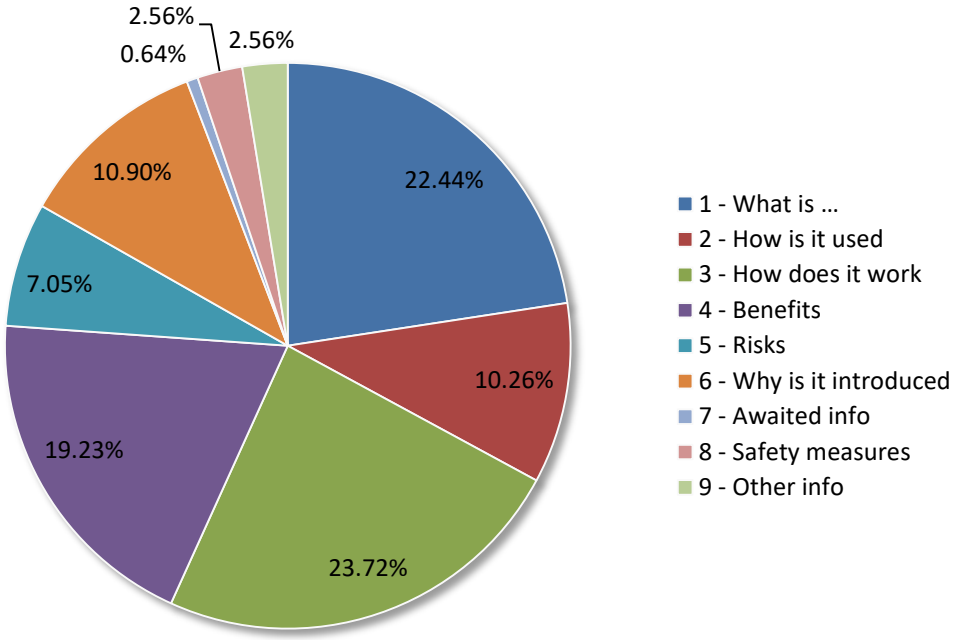
To take in review comments, we consider:

- 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



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:

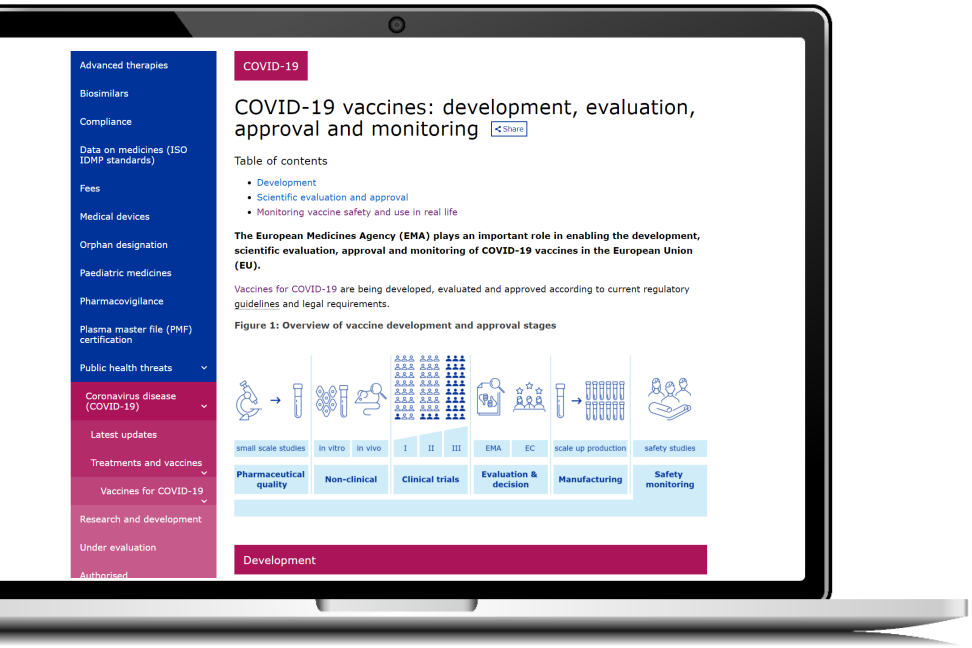
Key facts

PCWP involved in user testing and in EMAs pandemic task force

Published √

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

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



Published ✓

- 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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