EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

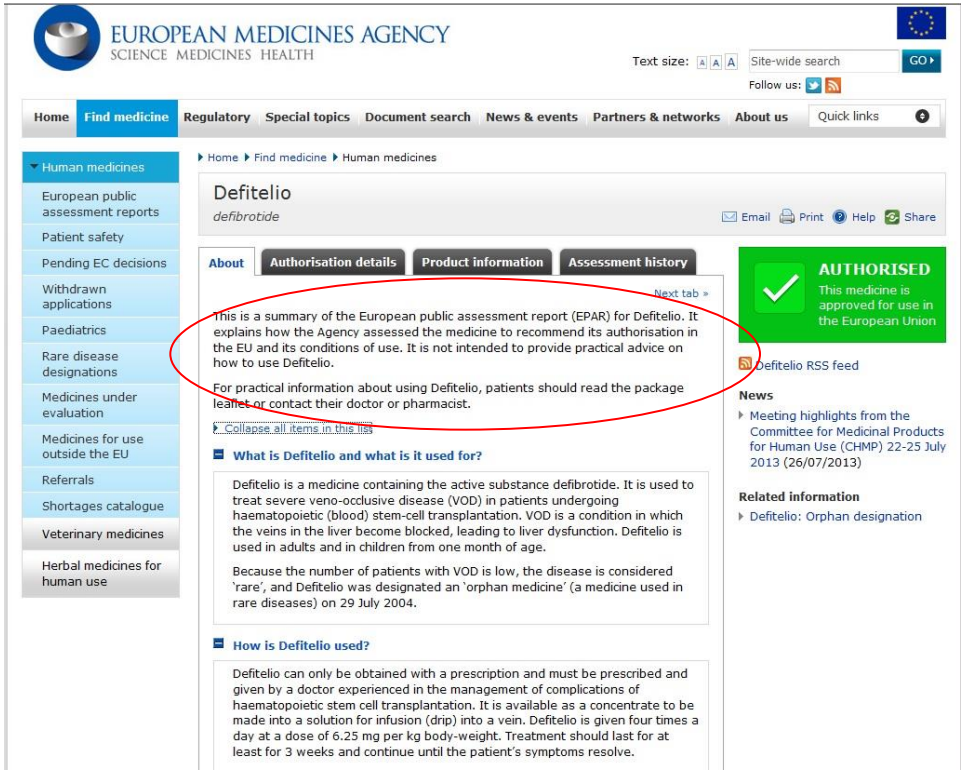
# EPAR summaries

Introduction to review by patients and consumers

Presented by: Paul Blake
Medical Writer/Stakeholder and Communications Division

An agency of the European Union

# What are EPAR summaries?




- Every centrally authorised medicine has its own page on the EMA website.
- The EPAR summary is the first thing you see when you look up a medicine: http://www.ema.europa.eu/ema/

# What are EPAR summaries?

- Each centrally authorised medicine has an EPAR, including:
  - product information
  - Assessment Report by the Committee for Medicinal Products for Human Use (CHMP)
- Summary is a short public-friendly document based on these, explaining the medicine and how it came to be approved
- Required by EU law (but the form isn't specified by legislation)
- Not a replacement for the product information (which includes SmPC and patient leaflet)
- A living document, which is kept updated throughout the lifecycle of the medicine

# Content of EPAR summaries

- What is the medicine and what is it used for?
- How is it used
- How does it work?
- What benefits have been seen in studies?
- What are the risks?
- Why has it been approved?
- What measures are being taken to ensure its safe and effective use?

# How EPAR summaries are prepared

- Documents
  - Product information
  - Adopted CHMP Assessment Reports
  - Internal style guide
  - Glossary of medical terms

# The review process

- Medical writers
- EMA product team
- Patient and consumer organisations
- Rapporteur and CoRapporteur (assessors)
- Company

# Why the review by patient and consumers?

- Patient/consumer perspective
- Patients and public concerns
- No source documents (check that it stands alone)
- Appropriate use of language
- Quality check

# Things to look out for

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

# Comments from patients and consumers

- All comments are considered
- Write what you think/feel
- Comments can be in any form:
  - General or specific
  - Text changes (tracked)
  - Suggestions
  - Questions

# Impact of review

- Around half of comments estimated to lead to text changes (not less than other reviews)
- Many implemented with modifications
- Some may not be implemented immediately but are used for changing templates and standard definitions

# Responses to feedback from patients and consumers

**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

# Responses to feedback from patients and consumers

**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 causing numbness, tingling and prickling sensations), 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.

# Responses to feedback from patients and consumers

- **What benefits of Harvoni have been shown in studies?**

Harvoni was investigated in three main studies involving a total of 1,952 patients infected with hepatitis C of genotype 1. In all three studies, the main measure of effectiveness was the number of patients whose blood tests did not show any sign of hepatitis C virus 12 weeks after the end of treatment.

In these studies, patients were given Harvoni, with or without ribavirin. After 8 or 12 weeks, around 94% to up to 98% of patients given Harvoni alone tested negative for the virus. The addition of ribavirin or extending treatment for more than 8 weeks was not needed for most patients. In one study, 97% of patients with liver damage achieved a negative test result after 24 weeks of treatment. Results of the studies also showed that patients whose virus ~~infection~~ was resistant to other antiviral medicines, achieve better results ~~could be better controlled~~ by extending treatment to 24 weeks.

Preliminary results from additional studies showed that Harvoni is also effective in patients with genotype 3 and 4, and that Harvoni in combination with ribavirin could be of benefit for patients with decompensated cirrhosis (scarring of the liver with reduced liver function) or for those who had received a liver transplant.

**Comment [SS5]:** "negative test result" may be misinterpreted. "tested negative for the virus" or something in that direction would be better.

**Comment [RGQ6]:** Taken. This section is now simplified and reworded.

# Responses to feedback from patients and consumers

- **What benefits of Harvoni have been shown in studies?**

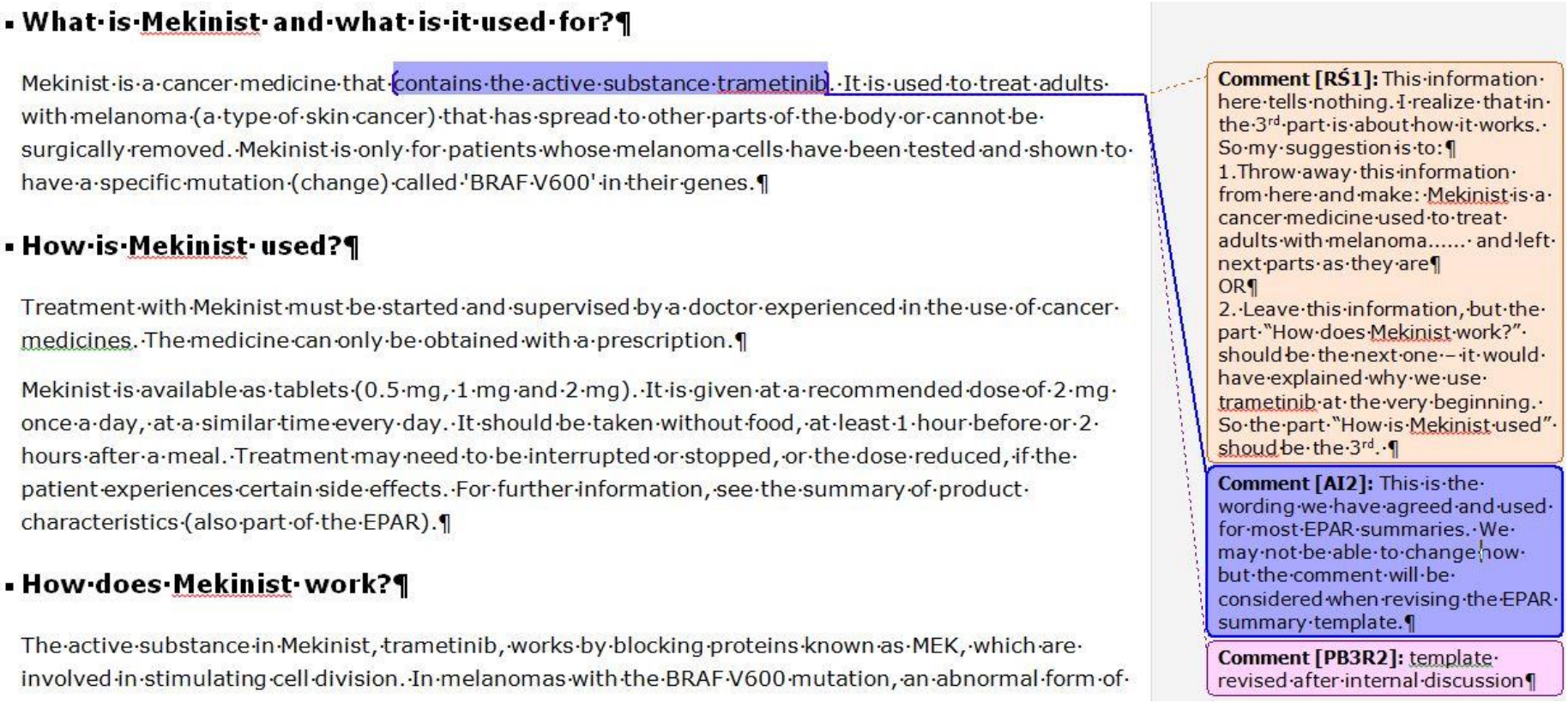
Harvoni was investigated in three main studies involving a total of around 2,000 patients infected with hepatitis C of genotype 1 who did not have failure of liver function. In all three studies, the main measure of effectiveness was the number of patients whose blood tests did not show any sign of hepatitis C virus 12 weeks after the end of treatment.

In these studies, patients were given Harvoni, with or without ribavirin, for 8, 12 or 24 weeks, depending on the characteristics of the patients. Around 94% to up to 99% of patients given Harvoni alone tested negative for the virus 12 weeks after the end of treatment. The addition of ribavirin was not needed for most patients.

Results of the studies also showed that patients who have compensated cirrhosis (scarring of the liver but who maintained liver function) had a higher likelihood of clearing the virus when treatment was extended to 24 weeks. Patients whose infection was resistant to other antiviral medicines could also benefit from extending treatment to 24 weeks.

Supportive data showed that Harvoni in combination with ribavirin would be of benefit for some patients with genotype 3 virus, as well as for patients with genotype 1 or 4 and decompensated cirrhosis (scarring of the liver with reduced liver function) and/or for those who had received a liver transplant.

# Responses to feedback from patients and consumers



- **What is Mekinist and what is it used for?**

Mekinist is a cancer medicine that contains the active substance trametinib. It is used to treat adults with melanoma (a type of skin cancer) that has spread to other parts of the body or cannot be surgically removed. Mekinist is only for patients whose melanoma cells have been tested and shown to have a specific mutation (change) called 'BRAF V600' in their genes.

- **How is Mekinist used?**

Treatment with Mekinist must be started and supervised by a doctor experienced in the use of cancer medicines. The medicine can only be obtained with a prescription.

Mekinist is available as tablets (0.5 mg, 1 mg and 2 mg). It is given at a recommended dose of 2 mg once a day, at a similar time every day. It should be taken without food, at least 1 hour before or 2 hours after a meal. Treatment may need to be interrupted or stopped, or the dose reduced, if the patient experiences certain side effects. For further information, see the summary of product characteristics (also part of the EPAR).

- **How does Mekinist work?**

The active substance in Mekinist, trametinib, works by blocking proteins known as MEK, which are involved in stimulating cell division. In melanomas with the BRAF V600 mutation, an abnormal form of

**Comment [RŚ1]:** This information here tells nothing. I realize that in the 3rd part is about how it works. So my suggestion is to:
1. Throw away this information from here and make: Mekinist is a cancer medicine used to treat adults with melanoma..... and left next parts as they are
OR
2. Leave this information, but the part "How does Mekinist work?" should be the next one – it would have explained why we use trametinib at the very beginning. So the part "How is Mekinist used" shoud be the 3rd.

**Comment [AI2]:** This is the wording we have agreed and used for most EPAR summaries. We may not be able to change now but the comment will be considered when revising the EPAR summary template.

**Comment [PB3R2]:** template revised after internal discussion

# Responses to feedback from patients and consumers

**What is Mekinist and what is it used for?**

Mekinist is a cancer medicine used to treat adults with melanoma (a type of skin cancer) that has spread to other parts of the body or cannot be surgically removed. Mekinist is only for patients whose melanoma cells have been tested and shown to have a specific mutation (change) in their genes called 'BRAF V600'.

Mekinist contains the active substance trametinib.

# Responses to feedback from patients and consumers

**What is Jevtana used for?**

Jevtana is used to treat men with hormone refractory metastatic prostate cancer. This is cancer that affects the prostate gland, the gland below the bladder in men that produces the liquid in semen. Jevtana is used when the cancer has spread to other parts of the body (metastatic) and does not respond to hormonal treatment (hormone refractory). It is used in combination with prednisone or prednisolone (anti-inflammatory medicines) in patients who have previously been treated with docetaxel (another anticancer medicine).

The medicine can only be obtained with a prescription.

**Comment [PE1]:** And do not react to docetaxel anymore

**Comment [DG2R1]:** It could be for other reasons such as that the side effects were too severe, so this has not been implemented to avoid too much detail.

# Conclusion

- Patients & consumers review an essential part of the process
- Aims include checking clarity, use of language
- Reviewers from patient & consumer organisations provide unique perspectives that improve the final document