EMA Training Programme

The meeting turned out to be a very complete training session. The EMA representatives explained what they do and how patients and health professionals may give feedback on the medicines being reviewed by Agency as part of certification and authorization process.
(See also the a set of explanatory videos on You Tube: https://www.youtube.com/watch?v=fC_4JD21F5E&feature=youtu.be)

Main points of the training session were the main activity areas of the EMA, in particular the Certification and Authorization of medicines seeking European authorization.
The programme then moved to a session with content specific to patients and patient organisations. In the later part of the session the EMA explained the importance of the feedback from patients associations and healthcare professionals.

The authorization of new medicines and the review of existing medicines. The session reviewed the ways in which patient collaboration is carried out. This session included:

- Medicine overview
- Safety communications, when there is something new on the medicine, not reported initially
- Shortage catalogue
- Medication error communications
- Herbal specifications
- Package specification

Patients' Associations specific session were also outlined:

- Once a Medicine is authorized the EMA publish on their website all info considered in the authorization decision (up to 200 pages from the medicine design to its testing and certification), excluding Pharmaceutical Confidential Information.
- Patients may access the sections that are more interesting for patient feedback like:
    - Example of Medicine overview – Ajovy - https://www.ema.europa.eu/en/medicines/human/EPAR/ajovy
    - A complex process continues with professional and public to check on medicines even after they are approved.
- Safety communication – both to inform regarding any potential issue or to inform of counter-indications after the verification process completed.
- Example: Fenspiride containing medicinal products https://www.ema.europa.eu/en/medicines/human/referrals/fenspiride-containing-medicinal-products
- Other info
    - Feedback procedures and timelines
    - Side effects
    - Some care giver information
    - Very different backgrounds of medicine reviewers
    - Some are patients and some not
- Example:

Examples

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.

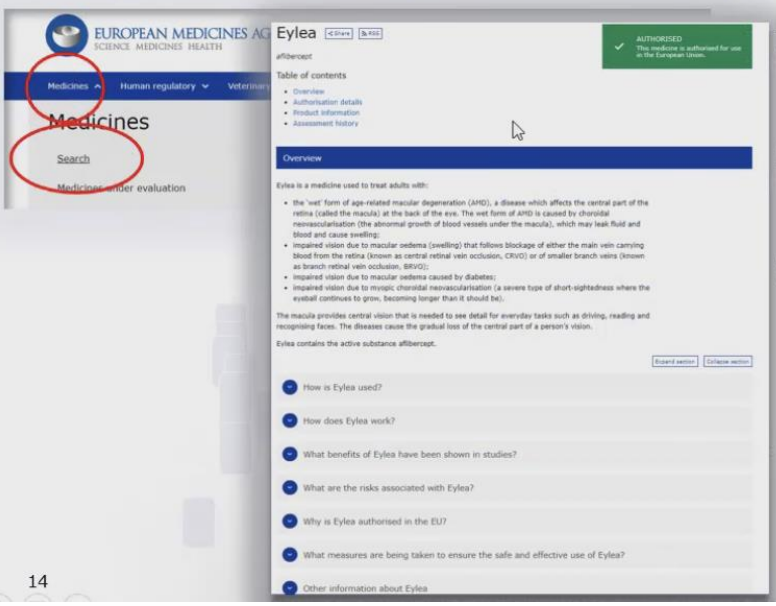
Comment [PE6]: What would be the effect on the patient? Pain?, tingling, numbness? I think that cn be added to make it more clear to the patient what it mean

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

- What happens after:
  - Feedback after check in EMA to the reviewer
  - Indication if will be or not be implemented
  - EMA may change accordingly, immediately or consider for future revisions
  - Send all suggestion, even if in doubt

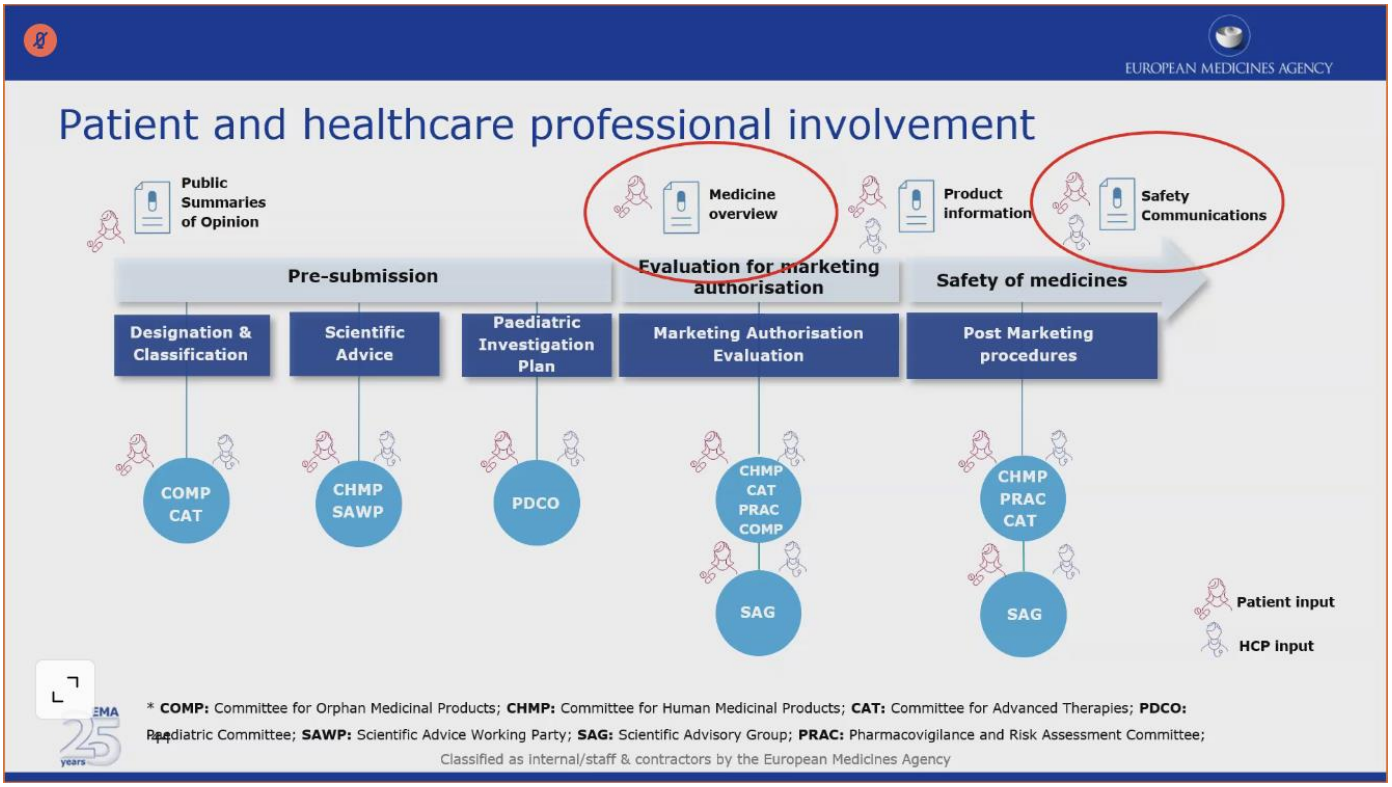
- Where are these documents on the website (also multilanguage):

Where can you find medicine overviews?



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

NOTE FROM EMA ABOUT ACCESS FOR PATIENTS TO THE FEEDBACK



1. Medicines assessed by EMA
The EMA receives applications from pharma companies for marketing authorization which permits sale of the drug. Not all are new medicines but existing approved medicines where the application is for a change of use. The session also explained how medicines may be used on compassionate grounds or 'off-label' use which is not in accordance so they are not yet on the market in principle.

Patients have an input to the authorization process through participation in various scientific committees of experts and patients. In Scientific Advisory Groups, patients are invited to provide their perspectives on what are the acceptable risks versus the benefits of the medicines as well as other aspects of the medicine.

2. Feedback from patients after market introduction
One of the major activities of the agency is Pharmacovigilance and Risk Assessment Committee (PRAC) – which monitors the safety of authorized drugs on the market. This Committee can recommend the withdrawal or suspension of medicines if concerns emerge. Patients can submit information directly to the health authorities that monitor the safety of medicines in each EU member state (http://www.adrreports.eu/) and it is also the possible to attend public hearing on particular medicines. All of this means that information about medicines on the market is constantly being gathered and assessed to be sure that the medicine continues to be safe – otherwise decisions are made on whether to change its availability. More information here.

Cosimo Pieri
Board Member