EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Workshop on the review of product information at the EMA by patients

EURORDIS Summer school 2015

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What information is available once a medicine is authorised?

A. Product information

- Part of the marketing authorisation
  - Legal basis
  - Agreed with the company during evaluation
  - Re-assessed and updated during medicine's life cycle
- Consists of:
  - **Summary of product characteristics** (SmPC)
    - Addressed to prescribers and pharmacists
  - **Package leaflet**
    - Addressed to patients (included in each package)
  - **Labelling**
    - Information on the outside of the packaging

What information is available once a product is authorised? (Cont.)

B. European Public Assessment Report (EPAR)

- Set of documents explaining how the Committee reached its recommendations
- Published for each centrally authorised medicine
- Consists of:

1. **Summary for the public**
2. List of authorised presentations
3. **Committee's assessment report**
4. Steps taken before and after authorisation
5. **Product information** (annexed)

Other documents prepared for the public

- **Safety communications** (convey an important (emerging) message relating to a medicine once authorised)
  - withdrawal or suspension from the market for safety reasons;
  - new contraindication or warning;
  - product defect
  - Potential supply shortage
- Other general communications
- Press releases

→ Decisions on communication are made on a case-by-case basis

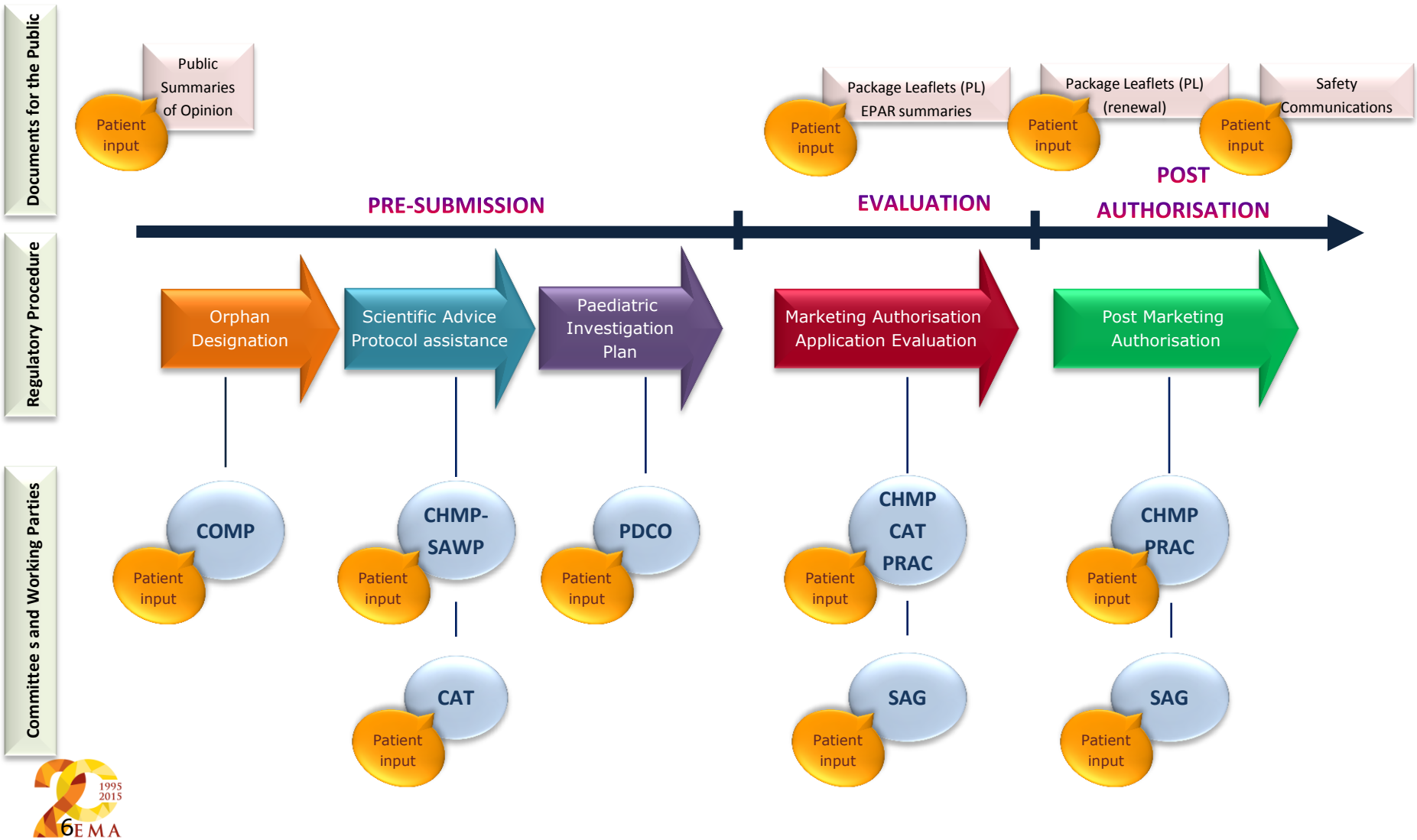
Publishing and sharing information

- All documents are published on Agency website
- Communications are actively sent out to mailing lists at time of publication
- Sent to patients' representative for further dissemination

Involvement of patients and consumers

- Patients and Consumers are involved in many aspects of the Agency's work
- Review of information on products since 2007
  - **Package leaflets**
    - newly authorised medicines
    - renewals of marketing authorisation
  - **EPAR summaries**
    - newly authorised
  - **Safety related communications**
    - all

Opportunities for Patient involvement along the medicine lifecycle at EMA



Principles for the involvement in review process

- The purpose of the review is to ensure that the information is clear and understandable for "lay people", and that it fulfils the public's needs in terms of information content
- All documents for review are confidential until they are made public; all experts must have signed confidentiality undertaking
- The documents are exchanged by Eudralink e-mail

What are EPAR summaries?

Ruconest

conestat alfa

This document is a summary of the European public assessment report (EPAR) for Ruconest. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Ruconest.

What is Ruconest?

Ruconest is a powder that is made up into a solution for injection. It contains the active substance conestat alfa.

What is Ruconest used for?

Ruconest is used to treat attacks of hereditary angioedema in adults (aged 18 years or over). Patients with angioedema have attacks of swelling that can occur anywhere in the body, such as in the face or limbs, or around the gut, causing discomfort and pain. Ruconest is used in patients with hereditary angioedema that is linked to naturally low levels of a protein called 'C1 esterase inhibitor'.

What are EPAR summaries? (cont.)

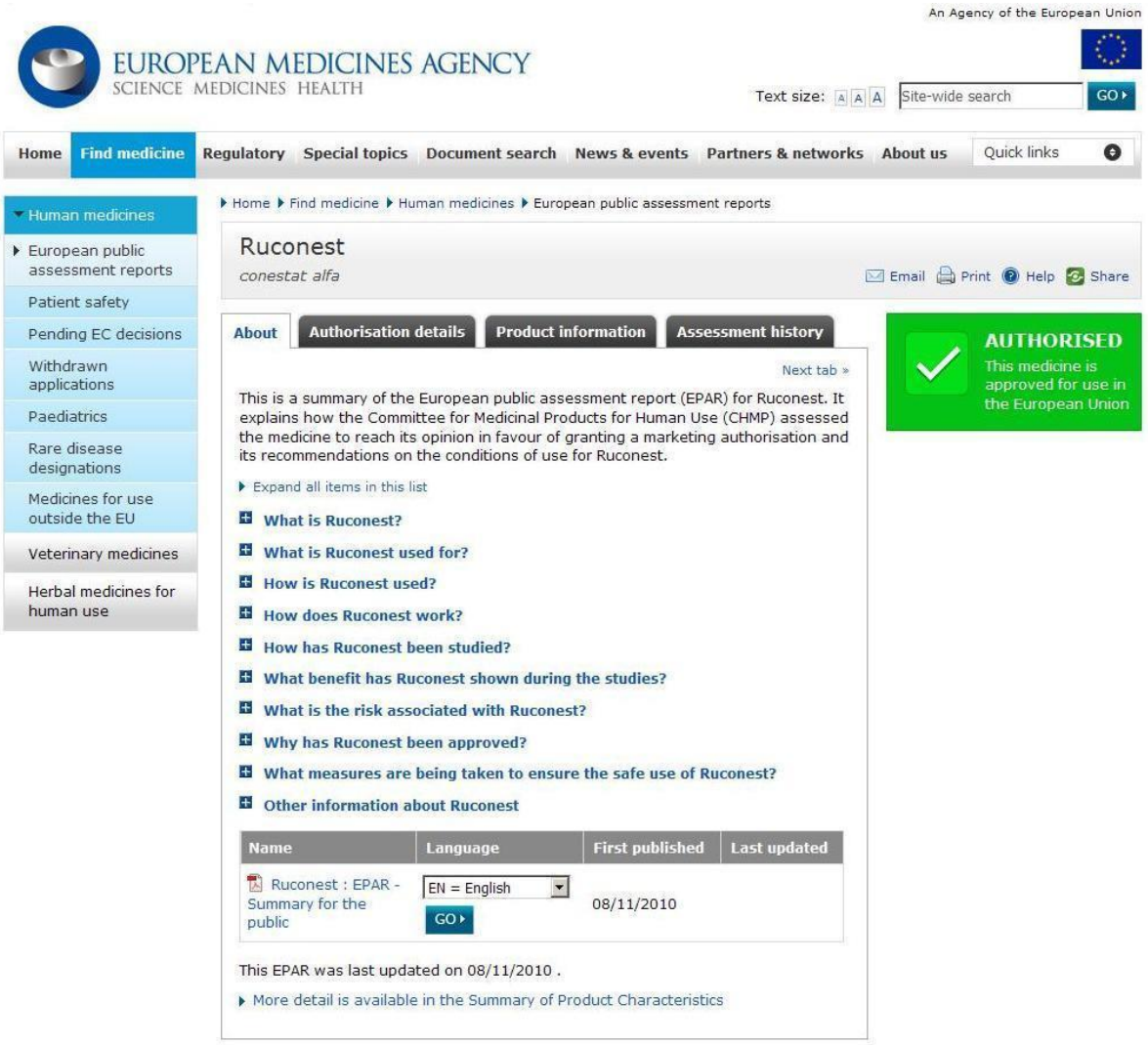
- They do not replace product information (which includes the package leaflet)
- Full EPAR includes product information as well as CHMP Assessment Report
- Required by EU law to be published along with the full EPAR

Other information about Ruconest:

The European Commission granted a marketing authorisation valid throughout the European Union for Ruconest to Pharming Group N.V. on 28 October 2010. The marketing authorisation is valid for five years, after which it can be renewed.

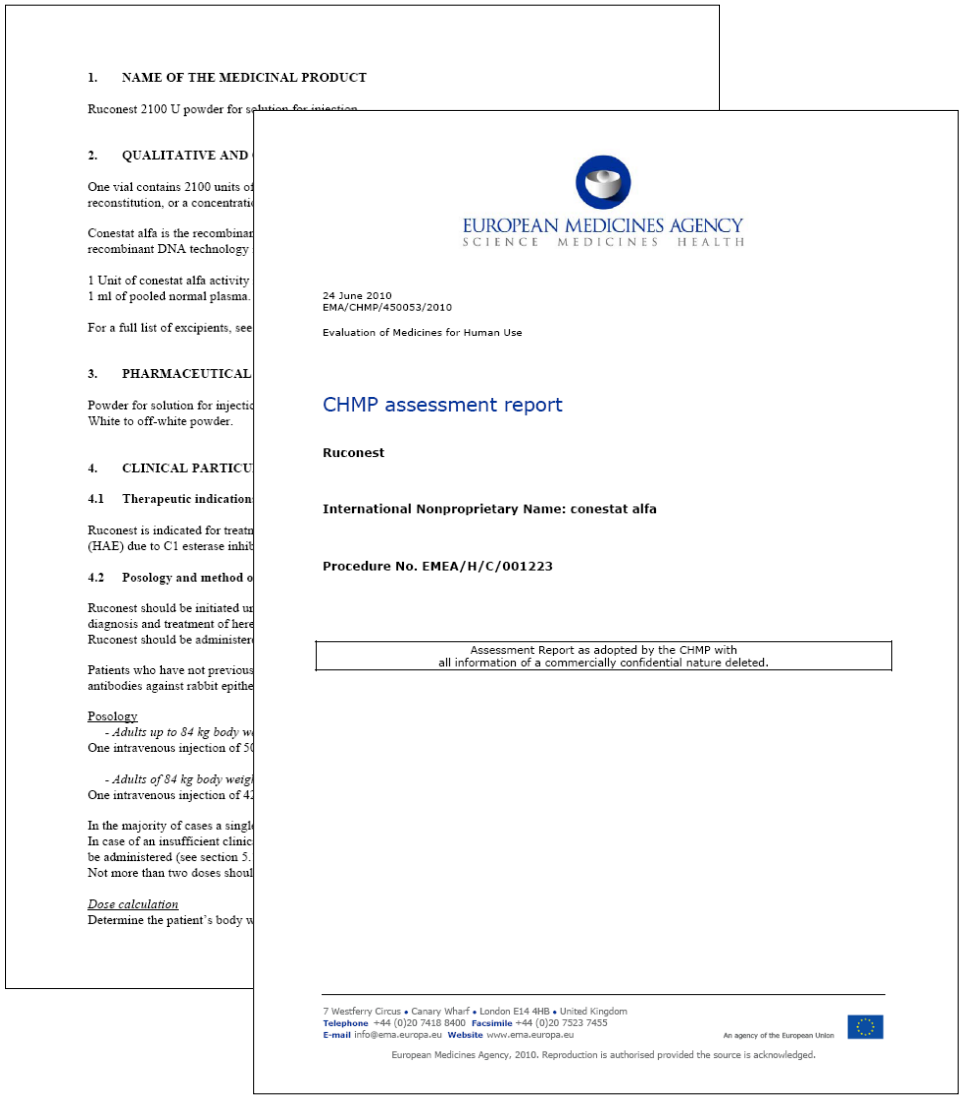
The full EPAR for Ruconest can be found on the Agency's website under EMA website/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Ruconest, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

Find medicine/human medicines/EPARs



How EPAR summaries are prepared

- Documents used for preparation
  - Product information
  - Adopted CHMP assessment reports
  - Internal style guide
  - Glossary of medical terms



1. NAME OF THE MEDICINAL PRODUCT

Ruconest 2100 U powder for solution for injection

2. QUALITATIVE AND

One vial contains 2100 units of
reconstitution, or a concentrati

Conestat alfa is the recombinan
recombinant DNA technology

1 Unit of conestat alfa activity
1 ml of pooled normal plasma.

For a full list of excipients, see

3. PHARMACEUTICAL

Powder for solution for injectio
White to off-white powder.

4. CLINICAL PARTICU

4.1 Therapeutic indication

Ruconest is indicated for treatm
(HAE) due to C1 esterase inhib

4.2 Posology and method o

Ruconest should be initiated un
diagnosis and treatment of here
Ruconest should be administer

Patients who have not previous
antibodies against rabbit epithe

Posology

- *Adults up to 84 kg body we*

One intravenous injection of 5

- *Adults of 84 kg body weig*

One intravenous injection of 4

In the majority of cases a singl
In case of an insufficient clinic
be administered (see section 5.
Not more than two doses shoul

Dose calculation

Determine the patient's body w

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 June 2010
EMA/CHMP/450053/2010

Evaluation of Medicines for Human Use

CHMP assessment report

Ruconest

International Nonproprietary Name: conestat alfa

Procedure No. EMEA/H/C/001223

Assessment Report as adopted by the CHMP with
all information of a commercially confidential nature deleted.

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The review process

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

Why the patient/consumer review?

- Patient/consumer perspective
- Patients and public concerns
- Only review without source documents
- 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?

Patient/consumer comments

- 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 patient/consumer review

- Comments are noticeably different from other reviews
- On average half of comments lead to text changes
- Many implemented with modifications
- Some not implemented immediately but are used for future reference for changing templates and standard definitions

Thank you

Any questions?