European Federation of Allergy and Airways Diseases Patients Associations

Being involved in EMA information to patients

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The origins of the involvement

Recommendations and Proposals for Action of the European Medicines Agency Committee for Medicinal Products for Human Use Working Group with Patients' Organisations (2005) – the forefather of the current Patients' and Consumers' Working Party

Need to have **independent and validated** information that is **patient-focused** and designed to **meet the needs of different user groups**

The origins of the involvement

Patients and consumers involved in reviewing:

→**Summary of European Public Assessment Report** (EPAR)

→**Package leaflets** for medicines

→Since 2010, **safety communications**

with the objective of ensuring readability and clear understanding of the public, improving the information aimed at patients for a safer use of the medicines & raising questions on unclear/missing information

Summary of EPAR

The European Public Assessment Report provides a comprehensive summary of available data on the **quality, safety and efficacy** of the product, justifying its authorisation and contains the product information and the summary

The **EPAR summary** is a lay-language document, which provides a summary of the grounds on which the Committee for Medicinal Products for Human Use based its recommendation for the medicine to receive a marketing authorisation

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EPAR summary for the public

Enurev Breezhaler
glycopyrronium bromide

This is a summary of the European public assessment report (EPAR) for Enurev Breezhaler. 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 Enurev Breezhaler.

What is Enurev Breezhaler?

Enurev Breezhaler is a medicine that contains the active substance glycopyrronium bromide. It is available as capsules containing a powder for inhalation.

Summary of EPAR

General elements of the content:

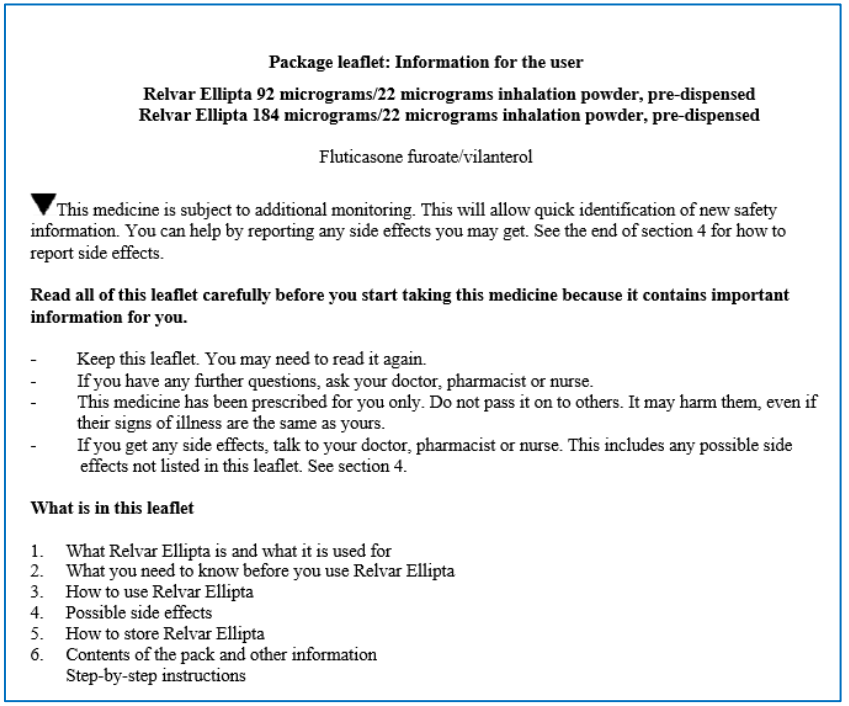
1. **What** is the medicine and what is it **used for**
2. **How** to use it
3. How the **medicine works**
4. What **benefits** of the medicines have been shown in studies
5. What are the **risks** associated with it?
6. **Why** the medicine is approved
7. What measures are being taken to ensure the **safe and effective use** of the medicine?
8. **Other information** about it

Package leaflets

The **package leaflet** is given to the patient in the package in which the medicine is contained, and provides information related to the use of the medicine

Contents:

1. **What** is the medicine and what it is **used for**
2. What you **need to know before** you use it
3. **How** to use it
4. Possible **side effects**
5. How to **store** it
6. **Contents** of the pack and **other information**



Package leaflet: Information for the user

Relvar Ellipta 92 micrograms/22 micrograms inhalation powder, pre-dispensed
Relvar Ellipta 184 micrograms/22 micrograms inhalation powder, pre-dispensed

Fluticasone furoate/vilanterol

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

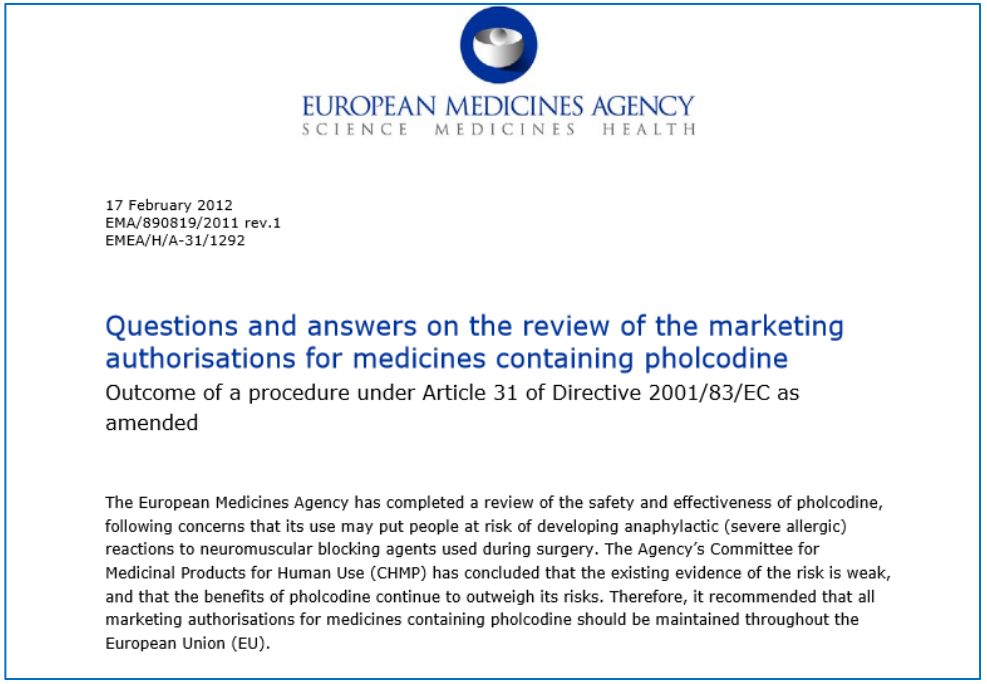
What is in this leaflet

Safety communications

Safety communications refer to documents addressed to the public to present an important emerging message on a specific medicine that is already in the market

Some examples:

1. **Withdrawal** or **suspension** of a product for safety reasons
2. New **contraindications** or **warnings**
3. **Defects in a product**



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Questions and answers on the review of the marketing authorisations for medicines containing pholcodine

Outcome of a procedure under Article 31 of Directive 2001/83/EC as amended

The European Medicines Agency has completed a review of the safety and effectiveness of pholcodine, following concerns that its use may put people at risk of developing anaphylactic (severe allergic) reactions to neuromuscular blocking agents used during surgery. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the existing evidence of the risk is weak, and that the benefits of pholcodine continue to outweigh its risks. Therefore, it recommended that all marketing authorisations for medicines containing pholcodine should be maintained throughout the European Union (EU).

General principles of involvement

- EMA consults **experts specialised in the therapeutic area of the medicine** & through nominated representatives of a patient group working with EMA
- **Only one round of consultation**; but the final version will be circulated for information among the reviewers
- EMA organises **annual training for patients and patients representatives to empower them** to take an active role
- All documents subject for review are **confidential** until they are made public

Special requirements for patients

- **English** as the only official language for reviewing documents
- Necessary access to **information technology equipment and Internet**
- **Strict deadlines** in some cases (e.g.: 3-4 hours in cases of specially urgent safety concerns)

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Frequently asked questions

How many documents to review?

Expert may receive 5-6 documents to review per year.

What are the deadlines?

For PLs and EPAR summaries, experts will have 10-15 days; for safety communications, deadlines are stricter.

How long to review the document?

Not more than 30 minutes-1 hour for EPAR summaries. PLs are longer, but not more than 1-2 hours.

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Thank you for your attention!

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