EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# What is a Package Leaflet – How to review it?

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# Legal background

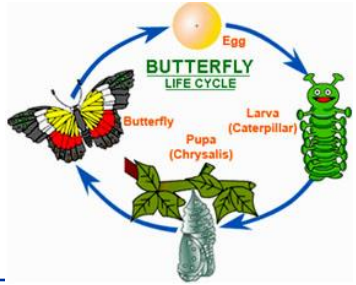
## ➢ Directive 2001/83/EC:

✓ The **inclusion** in the packaging of all medicinal products of a **package leaflet (PL)** shall be **obligatory.** (Art. 58)

✓ The PL must be written and designed to be **clear and understandable**, enabling the users **to act appropriately**, when necessary with the help of health care professionals. (Art 63.2)

✓ It also defines the information which has to be included in the Package leaflet (Art. 59)

# Lifecycle of the package leaflet (PL)




1) **The PLs are drafted by the pharmaceutical companies** based on their data

2) After submission of the dossier, starts a **number of rounds of review** involving different actors:

* Assessors from Member states
* EMA
* Patients

3) **Additional tool: User testing** (performed during a procedure): Legal requirement since 2005 - Not only looking at the content but also **at the design and lay-out** of the leaflet

Review of the PL can also occur for medicines already on the market

# Relevant documents for the PL

Regulators/companies use a number of documents when creating or reviewing up the PL.

- **SmPC (the basis for writing the PL)**
- **EC Guideline on the Readability of the Label and Package Leaflet (2009)**
- QRD template (annotated version) (QRD = document)

# Package leaflet structure and content

The QRD annotated template presents the structure and some guidance on the content of the package leaflet

**QRD PL Template** (annotated) created by the EMA

- ✓ based on EC Directive 2001/83/EC / EC Guideline /QRD Guidance
- ✓ based on model leaflet

**Regulary updated** based on Feedback received from publications, user testing experience, communication specialists, consumer associations, patients organisations, etc.

QRD template v9, 03/2013

# Patient Consultation: Process

In which cases : for package leaflets of centrally authorised medicines

-for new marketing authorisation applications and

-for renewal of marketing authorisations (5 years after initial authorisation)

How does it work: The package leaflet (together with Summary of Product Characteristic and labelling) is sent to the relevant organisation (depending on the indication of the medicine)

The organisation is usually given 10 working days to comment

What do we do with your comments:

LRS will validate the comments and transmit them to the applicant (sometimes to the assessors), without naming the organisation

# Patient consultation: What we expect from you?

- To make sure information is clear and understandable

- To raise any question on unclear/missing information

- To improve the information aimed at patients for a safer use of the medicines

# Conclusion

The independent insight of the patients in the review of PL has improved its readability and has stimulated scientific debate.

Thank You

Any questions?