



# Workshop on the patient's voice in the evaluation of medicines

Patient involvement in the PRAC

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# Patient involvement in the PRAC

## Scope of the presentation

### Communication and transparency aspects on patient involvement in the PRAC

- Role of the "generalist patient" in the committees

# Role of the patient representative in the PRAC

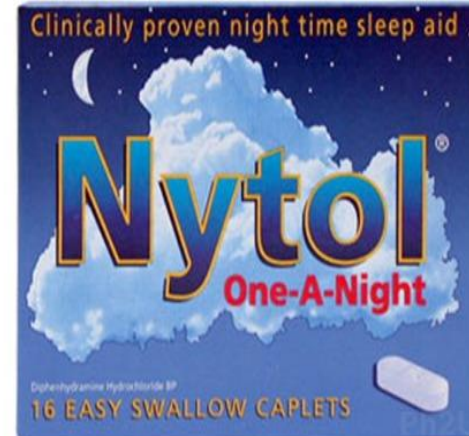
**Ensure that regulators remember for whom we are working so the scientific benefit-risk evaluation can be transformed to valuable information for patients in real life by**

- **providing input to the formulation of the text in the leaflet (PL)**

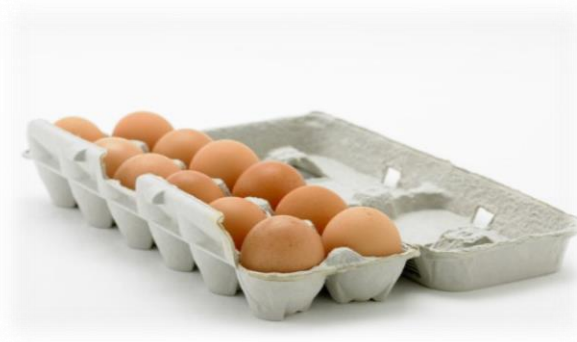
# "The hundred most stupid risk warnings"



**Label: Do not iron clothes on body**



**Label: May cause drowsiness**



**Label: This product may contain eggs**

# Role of the patient representative in the PRAC

- **contributing to**
  - the wording in the communication documents such as press releases and minutes and for example to remind of the importance of putting risk in perspective of benefit
  - decisions on timing of communication

Timing of risk communication is important! But not always so easy to decide when to communicate....





It is NOT a shark a it is a dolphin!



# Role of the patient representative in the PRAC

## Contributing by

- **identifying channels and patient and consumer organisations for dissemination of information**



# Role of the patient representative in the PRAC

## **The possibility to promote and raise awareness of the concept benefit/risk in patient and consumer organisations and consequently in the society**

- limited knowledge of the regulatory system in the society on concepts like benefit/risk and lifecycle e.g
  - is a suspension a failure of the system or part of a functioning system with reevaluation of a products benefit/risk after some time on the market?
  - the difference between benefits and risks on a group level vs for the individual patient

# Patient involvement in the PRAC

**In summary:**

**Patient involvement in committees like the PRAC is most valuable and will lead to**

- **increased public understanding of the benefit/risk concept and thus hopefully increased trust in the regulatory system and**
- **improved knowledge on the safe and rational use of medicines through better communication on benefits and risks**