

ELSC Meeting
6 December 2007

The Informed Patients: What the European Union has to do

Key issues of the statement of
Dr Hubertus Cranz
Director General of the Association of the
European Self-Medication Industry (AESGP)

- Non-prescription medicines are different from prescription medicines

- In regulatory terms:
 1. clear criteria for separating prescription/non-prescription medicines are incorporated in the EU legislation
 2. clear criteria for moving medicines from prescription to non-prescription status is in EU guidance document

⇒ Only low risk medicines may be non-prescription

- In commercial terms:
 1. High volume, low price
 2. Market share: 50% in volume, less than 20% in value

⇒ Political wish: expand responsible self-medication/self-care with the objective to:

 - a) better respond to the expectations of the citizens to take care of themselves
(consumer empowerment)
 - b) reduce cost burden for social security institutions

- Informed patients: What the European Union has to do

1. Regulatory side:

- Legislative framework: Although the industry could certainly see areas of improvement/deregulation, it is overall fine
- Problems with interpretation and implementation of EU legislation in some countries
- Main issue for AESGP: what kind of additional information is allowed
- Legal basis: Art. 62 allows symbols and pictograms on the label which are useful to help the understanding of information in line with the summary of Product Characteristics “...to the exclusion of any element of a promotional nature”. This applies to prescription and non-prescription medicines and whatever is mentioned is still controlled.
- A link to a website which may give additional information on how to cope with a condition could be helpful.
- Concrete example: The Summary of Product Characteristics of smoking cessation products contains advice that behavioural support is beneficial. Some companies offer online personalised stop-smoking plans. To enrol, people who wish to quit need to make a telephone call to obtain the web address. Placing the web address on the package would seem more reasonable.

2. Health policy side:

- Important role of health professionals: pharmacists and medical doctors
- Education highly important to allow best possible communication on self-care related matters
- Adjustment of curricula possible, use existing options
- Sufficient awareness in post-graduate training
- Create adequate pharmacy layout

⇒ Without better information, the benefits of responsible self-medication cannot be fully realised.