



European Life Science Circle

**“High quality information to
Patients and possible role
of EMEA”**

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- Information on medicines is a fundamental right to Patients
- High quality information reinforces the concept of patient empowerment
- High quality information promotes safe and rational use of medicines
- All EU Patients must have equal access at any time to high-quality, objective, reliable and non-promotional information on medicines



How are the players in information to patients

- Central- regional- local
- Governments- EU
- Regulatory agencies
- Pricing and reimbursement agencies
- Health technology assessment agencies
- Independent organisations including patients
- Industry
- Distribution
- Health care professionals



The role of the EMEA

Mandate in the revised pharmaceutical legislation

To develop and adapt EMEA information practices to the needs and expectations of the Agency stakeholders (Patients and health care professionals)

To reinforce the partnership of the EU regulatory system network with the aim of providing the best possible information on medicines at European level



Electronic information tools

- EMEA website (to be adapted to patients' needs)
- EU information source:
 - EudraCT
 - EPAR (benefit/ risk) and PIL
 - EudraVigilance
 - EudraPharm (centralized products and national?)
 - Actual updated information about warnings etc
 - Q and A documents
- EMEA to ensure all electronic tools fit together in a coherent way



Non-electronic tools (I)

Their role is still crucial (*i.e.* disabilities, elderly, people without access to Internet, etc)

One example: the actual Package Leaflet:

- ✓ Essential non-electronic information tool
- ✓ More information could be included on it (as proposed by the EMA/CHMP Working Group with Patients Organisations in their “Recommendations and Proposals for Action” (*EMA/149479/2004 Final*) with regard to Product information)



Non-electronic tools (II)

Examples of information that Patients would like to have in the PL:

- ✓ A good balance between information on the expected benefits for a Patient with a specific condition versus the risks of taking the medicine.
- ✓ Especially relevant for long term treatment and prevention: it would be expected to increase compliance
- ✓ Information to allow better distinction between prevention and treatment
- ✓ A recommendation in the event that the expected benefit is not achieved

Thank you

Any questions ?

