



EMA/CHMP Working Group
with Patients' Organisations
- WORKSHOP 3 DECEMBER 2004 -

Recommendations and Proposals for Action

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Concluding Remarks



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Recommendations in the Area of Mandate/Composition of the WP

Before any Action, the EMA should ensure that the
Organisation fulfills criteria allowing/ensuring its :

- Identification/Legitimacy/Representativity
- Missions/Structures/Actions
- Internal Consultation modalities/Transparency



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Recommendations in the Area of Transparency & Dissemination of Information

Patients need 'independent (validated)' information

- to understand/participate in their treatment

All partners should collaborate in this process but EMA:

- has herein a special role to play ('validated')
- should reinforce the patient-focused items
- needs to consider more communication tools (>web)



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**Recommendations in the Area of
Interaction between EMA/CHMP &
Patients' Organisations**

EMA should:

- establish a policy to communicate with patients (see roadmap)
- define different frameworks to communicate with the view
 - to better understand the impact of a disease,
 - and its management (in a patient's perspective)
- invite patients as experts, as needed, following clear predefined provision (CoI)
- organize training to facilitate understanding of the system



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**Recommendations in the Area of
Product Information**

EMA should:

- interconnect European patients' associations with/to NCA websites
- link P(i)L and updated version on the website
- liaise with patients on P(i)L matters (feed back-readability)
- catalyse an harmonized content of the P(i)L
- consider achieving improvement and implementation of a revised future legislation



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**Recommendations in the Area of
Pharmacovigilance**

- EMA should more closely consider the « spontaneous reporting » as an upcoming tool
- Epidemiology studies and Risk Management programmes acknowledged by patients need to be encouraged
- Performant channels to deliver novel information to Healthcare Professionals should be developed
- Communication should not jeopardise therapeutic adherence, as appropriate



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**Thank you for your
participation**