



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

**Recommendations in the area
of interaction between
EMA/CHMP and Patients'
Organisations**

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**Comments received and discussed by
the working group:**

CPME, ECPC, EGA, EPFA, PGEU, EFPIA,
MSD, Eurordis, Ministry of Health-Czech
Republic, Ministry of Health-Germany.



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**General comments already discussed in
the introduction and addressed in the
EMA Road Map to 2010:**

- Acknowledgement of the role of the Physician and the Pharmacist
- Greater Patients' involvement in the CHMP activities



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Introduction to our main proposals

- Policy on involvement of Patients' and Consumers' Organisations in the EMA activities:
 - > Not modified
- Framework for interaction with Patients as experts or representatives of their organisations:
 - > Modified to introduce the added value of patients participation, balance between confidentiality and share of information and adherence to EMA policy on declaration of interests



Introduction to our main proposals

- Organisation of training to provide regulatory background to Patients (new point)
- Public hearings: need for further debate due to divergent views



Conclusions

All these points are priorities on the 2005 agenda of the Working Party with Patients' Organisations