



General remarks on the recommendations

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meetings with patient organisations

- ⌘ objectives
- ⌘ background information
- ⌘ my observations
- ⌘ comments from stakeholders
- ⌘ next steps



objectives

- ⌘ improve connections with patients
- ⌘ improve information to patients
- ⌘ learn what are the needs of patients
 - ✓ information
 - ✓ better use of medicines
 - ✓ contacts with regulatory agencies



background information

- ⌘ first meeting with patients may 2002
- ⌘ start working group may 2003
- ⌘ meetings in September, December 2003 and February, June, August and October 2004

invited organisations

- ✓ BEUC Bureau Européen des Unions de Consommateurs
- ✓ EATG European AIDS treatment group
- ✓ EFNA European Foundation of Neurological Association
- ✓ EPHA European Public Health Alliance
- ✓ Eurordis European Organisation of rare Disorders
- ✓ IAPO International Alliance of Patients Associations
- ✓ EFP European Patients' Forum
- ✓ ECL European Cancer league

observations, negative

- ⌘ hesitations by regulators on what can be reached
- ⌘ regulators: patients not competent to take part in scientific discussions



observations, positive

- ⌘ active participation of patients
- ⌘ high competence of the patients representing
- ⌘ express strong wish to get more information
 - ✓ balanced information (PL)
 - ✓ objective
 - ✓ in patients language

observations, concerns

- ⌘ giving feedback on time (timetables)
- ⌘ proper feedback to and from the organisations they represent
- ⌘ reality of volunteer organisations
 - ✓ payment of the work performed



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comments on recommendations

- ✓ general comments
- ✓ detailed comments
 - interaction CPMP / EMA with patients
 - pharmacovigilance
 - package leaflet / patient information leaflet
 - transparency and information



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comments on recommendations

- ✓ welcomed the initiative
- ✓ should not interfere doctor patient relationship
- ✓ role of community pharmacist
- ✓ want direct involvement in the process (industry)



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comments on recommendations

- ✓ EMA should be the co-ordinating centre
- ✓ role of the EMA vs. national authorities
- ✓ sufficient resources
- ✓ the need of setting priorities



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comments on recommendations

- ⌘ urgent need of information to patients
- ⌘ balanced information
 - ✓ patient want more information on benefits
 - ✓ to much stress on side effects and warnings
 - ✓ doctors: afraid for advertising
 - ✓ remember: improve compliance



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comments on recommendations

- ⌘ active participation of patients
 - ✓ patient as representatives of their organisations
 - ✓ patients as experts in (scientific) discussions
- confidential agreement necessary*



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comments on recommendations

- ✓ clear definition between boundaries between transparency and confidentiality
- ✓ more pharmacovigilance information
- ✓ development of medical information expertise
- ✓ alternative tools for dissemination of information



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comments on recommendations

- ✓ independence of patient organisations (funding)
- ✓ transparency of funding and governing of the patient organisations
- ✓ working group preparing policy document



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next steps after this workshop

- ⌘ implementation of recommendations
- ⌘ starting a permanent CHMP /EMA working party with patient organisations
- ⌘ policy document for patient organisations
- ⌘ addition of other organisations