

- WORKSHOP 3 DECEMBER 2004 -

General remarks on the recommendations

Frits Lekkerkerker

Co-chairman of the working group

Dutch alternate CHMP member



EMEA/CHMP Working Group with Patients' Organisations

- WORKSHOP 3 DECEMBER 2004 -

meetings with patient organisations

₩ objectives

₩ background information

₩ my observations



EMEA/CHMP Working Group with Patients' Organisations

- WORKSHOP 3 DECEMBER 2004 -

objectives

- ₩ improve connections with patients
- ₩ improve information to patients
- $\ensuremath{\mathbb{X}}$ learn what are the needs of patients
 - \checkmark information
 - √ better use of medicines
 - √ contacts with regulatory agencies



EMEA/CHMP Working Group with Patients' Organisations

- WORKSHOP 3 DECEMBER 2004 -

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



- WORKSHOP 3 DECEMBER 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

 $\checkmark\,$ Eurordis European Organisation of rare Disorders

✓ IAPO International Alliance of Patients Associations

✓ EFP European Patients' Forum ✓ ECL European Cancer league

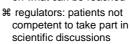


EMEA/CHMP Working Group with Patients' Organisations

- WORKSHOP 3 DECEMBER 2004 -

observations, negative

無 hesitations by regulators on what can be reached無 regulators; patients not







EMEA/CHMP Working Group with Patients' Organisations

- WORKSHOP 3 DECEMBER 2004 -

observations, positive

- ₩ high competence of the patients representing
- $\ensuremath{\mathbb{X}}$ express strong wish to get more information
 - √ balanced information (PL)
 - √ objective
 - √ in patients language



EMEA/CHMP Working Group with Patients' Organisations

- WORKSHOP 3 DECEMBER 2004 -

observations, concerns

- ₩ giving feedback on time (timetables)
- $\ensuremath{\mathbb{X}}$ reality of volunteer organisations
 - ✓ payment of the work performed



- WORKSHOP 3 DECEMBER 2004 -

comments on recommendations

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



EMEA/CHMP Working Group with Patients' Organisations

- WORKSHOP 3 DECEMBER 2004 -

comments on recommendations

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



EMEA/CHMP Working Group with Patients' Organisations

- WORKSHOP 3 DECEMBER 2004 -

comments on recommendations

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



EMEA/CHMP Working Group with Patients' Organisations

- WORKSHOP 3 DECEMBER 2004 -

comments on recommendations

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



- WORKSHOP 3 DECEMBER 2004 -

comments on recommendations

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



EMEA/CHMP Working Group with Patients' Organisations

- WORKSHOP 3 DECEMBER 2004 -

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



EMEA/CHMP Working Group with Patients' Organisations

- WORKSHOP 3 DECEMBER 2004 -

comments on recommendations

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



EMEA/CHMP Working Group with Patients' Organisations

- WORKSHOP 3 DECEMBER 2004 -

next steps after this workshop

- lpha implementation of recommendations
- ℜ starting a permanent CHMP /EMEA working party with patient organisations
- ₩ policy document for patient organisations
- ₩ addition of other organisations