



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA-PDCO (PaeDiatric Committee)

HCP meeting 4 March 2020

Presentation: Johannes Taminiau



PDCO and HCP

HCP's for doctors 6 members, for patients 6 members as part of PDCO

Task expert advise for Pediatric Investigation Plans (PIP's)

Decision in 30 days in procedures discussed

Full participation of HCP's in PIPs needed for useful impact, just advise insufficient

Expert outside PDCO HCP/member experts advise identical issue, to be useful needs

Development of criteria, standards, new classifications

Writing position papers for "Design for clinical studies with drugs for pediatric diseases"
by EMA PDCO with academia

Examples: Cystic Fibrosis, Intestinal Adenomatous Polyposis, IBS, Functional Constipation, IBD, Familial Hypercholesterolemia, Hepatitis B and C

Last year improvements: SAWP

PIP investigation problems Scientific Advice might be sought

HCP consulting needs more active participation to optimize PIP

Enormous increasing SA numbers load needs full country MEB involvement for PDCO members

Effective needed input from HCP experts in progress

New initiatives: CAT

New collaboration with PDCO

Adeno Virus Vector (AVV) therapy in children: what are the risks

Liver development with episome loss after higher liver cell division with dilution effect over time in children

No data available on liver development

PDCO HCP initiative to develop needed information on liver development