European AIDS Treatment Group

Workshop on PSP & MSP

Reflections from the patient side

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General

- PSP & MRP are meaningful, especially when new drugs & interventions are being introduced
- Good example: HCV DAA
- MAH should know & understand what patients are going through or why treatment is challenging (pill size, swallowing not easy, drug tastes bad etc)
- PSP & MR run by MAH marketing departments

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PSP

- Definition: no comment
- Has to serve a clear purpose & not become a bureaucratic monster
- PSP & MR will not qualify as a respectable safety study
- No SUSAR will be detected
- EMA & FDA should agree on classification of „solicited“ results
- PSP reports = consumer reports
- Good to assess impact of safety data from PSP

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Conclusions

- We don’t consider such programmes to be high quality safety data sources
- Such data coming from
  - Patient cohorts
  - PASS, specifically designed safety studies
  - HCP channels, direct consumer reporting
- Agencies should focus on high quality data
- Difficult to understand why PSP & MR could be subject of inspection – rather be nervous about supply chains

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