

Patients' Organisations use of EudraVigilance



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From a patient

- M., ♂, 29 y-old, acute pain after motorbike accident
 - No more Diantalvic
 - Tramadol prescribed instead
 - Severe anxiety, nightmares, suicidal ideation
 - Firstly: psychological reaction to accident
 - Secondly: read the notice
 - *Rares ($> = 1/10000$, $< 1/1000$)*
 - ➡ Wanted to check more info about it, but where?
 - ➡ Wanted to report personal experience, but where?
 - "Ne consommez pas d'alcool pendant le traitement par Tramadol sandoz LP car cela accentuerait son effet"



Public access to Eudravigilance

- Is a success
 - It responds to our recommendations 2004
 - EMEA/CPMP Working Group with Patients' Organisations – Outcome of discussions: Recommendations and proposals for actions – 20 April 2004
- Is a progress
 - 27 EU, 40+ public fields
- Is a hope
 - More rapid detection



What can we do?

- Work with national authorities to organise self-reporting (MS web portal)
- Explain our public how to use Eudravigilance
- Advise EMA how we would like Eudravigilance data be displayed
- Encourage our public to always report ADRs



And also?

- Use reporting of ADRs to gather information that is usually not collected
 - E.g. Concomitant use with illicit products
 - E.g. Off label use

- 353 registries on rare diseases
 - How to relate them to EudraVigilance?