

Geriatrician's perspective on implementation of the new pharmacovigilance legislation.

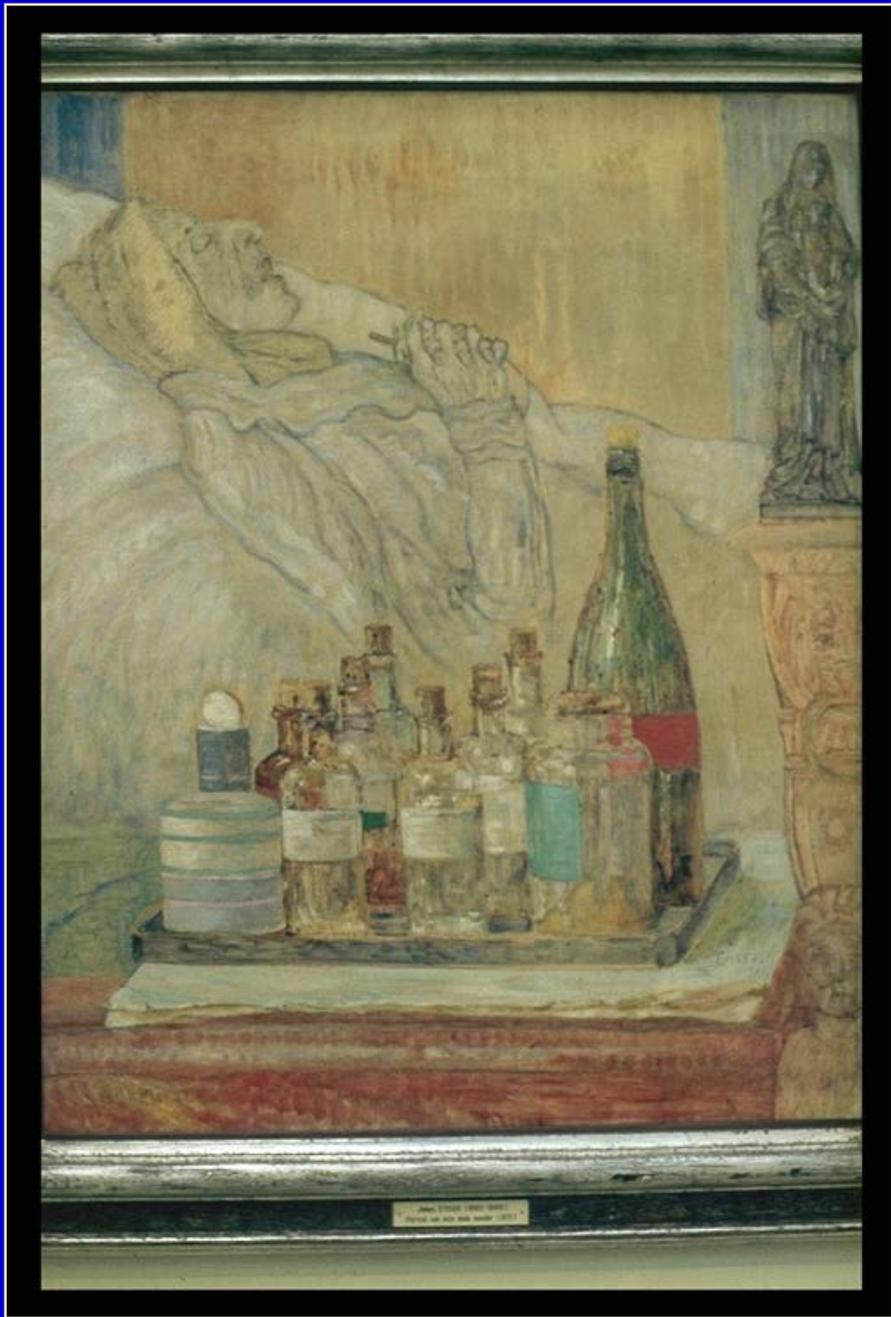
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The daily reality !





Pharmacovigilance is needed!

- NEJM 1999 Spironolactone decrease mortality and morbidity in patients with severe heart failure...., BUT older patients develops hyperkalemia...
- New oral anticoagulants causes frequently major bleedings in the oldest old patients...

“Before a medicine can be authorised and made available to patients, clinical trials must be carried out to show that it is safe and effective **IN REAL and REPRESENTATIVE PATIENTS.**”

“All suspected side effects should be reported, even if their association with a medicine has not been confirmed.”

Number of reports in Belgium 2012

Age category	Number of reports	% of reports	% of the population
0-12	255	7%	15%
13-17	79	2%	6%
18-39	545	15%	28%
40-64	1409	37%	34%
65-79	1032	27%	12
≥80	458	12%	5%
Total	3778	100%	100%

Pharmacovigilance is difficult in older patients → underestimated !

- Many ADR's are considered as “ageing” problems , and are often “atypical”;
- The polypharmacy...
- The multiple comorbidities...
- Rather difficult to receive precise information from the patient/carer (less educated people, dementia, etc)...
- The shortage of staff in all settings....

The problem with copies and generics...

- Bioequivalents or generics have different commercial names: some patients are taking twice the maximal dosage!

Reports of ADR's by the MD.

- Only when the MD find the ADR “relevant(??)”.
- Only when the MD is 100% convinced of the ADR or when a re-challenge is successfully performed.

→ Most of the ADR are never reported...

Pharmacovigilance is a “problem” in older people.

- The endpoints became with increasing age “different”.
 - 5 year survival is an excellent indicator in young adults, but at the age of 92...??? There the QUALITY of LIFE is the MOST important matter..
 - Improving quality of life is for these oldest older people more important than their survival...

Take Home Messages

- The ADR's are more frequent with increasing age, but the reality is much more important than the figures.
- Closer Pharmacovigilance is needed in the oldest age group.
- Clinical trials in the oldest age groups with different endpoints are urgently needed, and can not be replaced *by Post-authorisation safety studies or Pharmacovigilance.*