Pharmacovigilance for New Medicines and Novel Regimens, and Established Medicines and Regimens

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Burglars are not a problem anymore here, but can she still safely sleep?
Does this count as an adverse effect?

Drug Co.
CUSTOMER SERVICES

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... you're right, morphing into a hideous monster is not listed as a possible adverse reaction.
FDA HEARINGS

WHY DON'T YOU LET THE MARKET DECIDE IF A MEDICINE IS SAFE??!!

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RECALL

Benadryl

ALLERGY

For Allergy Relief

FRESHMINT

Tylenol Extra Strength
When GOOD MEDICINES Become BAD Drugs
Why to do TB pharmacovigilance?

- Off-label use in MDR-TB management
- Shorter regimens for MDR-TB
- Compassionate use
- New TB medicines conditionally approved
- Planning/budgeting TB control
- Public confidence/ NTP credibility

Alongside the measures in 3. above to monitor treatment adherence and effectiveness, special vigilance is needed for adverse events, including potential reactions to delamanid which are as yet undescribed.
Bottomline!

- Patients suffer without treatment
- Treatment should not worsen their suffering, unnecessarily!
Objectives

• Raise awareness of SIAPS pharmacovigilance for TB (PV for TB) activities and tools available for ensuring patient safety

• Determine the level of PV for TB in each country

• Discover how SIAPS and our partners can provide assistance